ADVERSE REACTION TRACKING

USER MANUAL

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GMRA*4.0*21

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Preface

This manual was developed to assist the clinical users of Adverse Reaction Tracking (ART). This manual shows how the Adverse Reaction Tracking software appears to the clinical user, and gives basic instructions on its use, through ART options in character-based VistA, as well as in the character-based and graphic user interfaces of the Computerized Patient Record System (CPRS).

The objective of ART is to track and report patient allergy and adverse reaction data. The software contains parameter fields that the site can use to customize the use of the software to the site's needs.

Revision History

Revision Date	Page or Chapter	Description
December 2004	Throughout manual.	Edits based on SQA review, including removal of Marked on Chart prompts.
November 2004	Pages 1 and 39	NKA deletion enhancement added
October/November 2004	Throughout manual.	Patient name and SSN and provider name updates to comply with Patient privacy SOP.
October 2004	Appendix 3	CPRS GUI 25 Release Notes for ART added and updated.
January 2004	Page 24	Patch 17 (GMRA*4*17) Free Text Allergy Clean Up Utility info added.

Table of Contents

Introduction

The objective of ART is to track and report patient allergy and adverse reaction data. This is accomplished through three interfaces:

1. ART menus and options within character-based VistA
2. Character-based CPRS
3. CPRS GUI

Today, most clinicians probably review and record patient allergy and adverse reaction data through the CPRS GUI. Several changes to the program have occurred recently. Free-text allergies may no longer be entered through CPRS. At sites that have installed OR*3.0*195, OR*3.0*216, and GMRA*4.0*21, CPRS users can no longer enter allergies and adverse reactions as orders that are placed in the *ORDERS* file, and allergies do not appear on the Orders tab. Patch OR*3.0*216 includes a post-installation routine that changes the status of all active allergy orders to complete and, therefore, removes the allergy orders from the Orders tab.

In addition, users can no longer select OTHER ALLERGY/ADVERSE REACTION as a type of causative agent, nor can they select OTHER REACTION as a type of sign/symptom. Changes to the ART package have eliminated these items as choices. These changes mark a continuing effort to end free-text and unspecific entries.

CPRS GUI 24 introduced a dialog through which users can request that a causative agent be added to their site's *ALLERGIES* file. Users access this dialog via a warning that pops up when they attempt to enter a free-text causative agent. The warning dialog asks users to indicate— by clicking either its YES or NO button—if they want to send a causative-agent inclusion request. In CPRS GUI 24, the default button was YES. In this version, the default button is NO. Furthermore, when users click the system X button (located in the top right-hand corner of each screen) to exit any of the screens that comprise the inclusion-request dialog, CPRS now cancels the request action.

NKA: It is now possible to delete an assessment of NKA from within the ART package. When you select a patient for entering/editing allergies and that patient doesn't have any active allergies on file, the "Does this patient have any known allergies or adverse reactions?" prompt is presented to you. If the patient has no assessment, there is no default answer. If the patient has been assessed as NKA, the default is NO. In the case where the default answer is NO (meaning, the patient is NKA), you may enter an @ sign to indicate that the assessment should be deleted and the patient should be returned to the 'not assessed' state. This would be used in those rare cases where an assessment is erroneously assigned to the wrong patient.

Use of ART within CPRS is primarily described in CPRS documentation, but some examples are provided in this manual.

The four major components of the ART package are:

1. Data Entry Options - Adverse Reaction Tracking has two options where a user can enter data.

a. Enter/Edit Patient Reaction Data - This option allows the clinical users (i.e., doctors, nurses, other clinicians and clerks) to enter data into ART.

b. Verify Patient Reaction Data - This option allows the verifiers designated by ART to verify the correctness of data entered by the clinical users into ART. This option does NOT perform evaluation of suspected Advanced Drug Reactions (ADR) as described in Section 5.a.(2).(d) of Directive 10- 92-070.

2. Reporting options - These options report the patient causative agent data to you via a print option. Also, this data is made available to other software applications via a data extract utility.

3. Enter/Edit Site Configurable Files - This menu allows the various site configurable files to be modified to allow ART to better meet the needs of an individual site.

4. Adverse Drug Reaction (ADR) options - These options support implementation of Directive 10-92-070. It allows for the evaluation of a suspected ADR by a qualified individual (e.g., clinical pharmacist, clinical pharmacologist) other than the attending physician, as specified in Section 5.a.(2).(d) of Directive 10-92-070. This component also generates the reports needed by the FDA.

There are four major users of the software:

1. Clinical users - These are the doctors, nurses, other clinicians, and clerks entering the data into ART. They are required to enter data pertinent for a particular allergy/adverse reaction. If the allergy/adverse reaction was observed at the site, data pertaining to any possible legal action could be tracked. This data would then be made available to users of any service using the Reporting options, thus avoiding any errors in care. Two other data elements that are tracked are the date/time that the patient chart was marked and the date/time that the patient ID band was marked, indicating the patient's reaction to the particular causative agent. Automated mail bulletins are sent to the appropriate users when the date/time patient chart marked data field has not been recorded.

2. Verifiers - These are designated users by the site who verify the correctness of the data in ART. The verifiers are designated when the Information Resources Management Service (IRM) allocates the GMRA-ALLERGY VERIFY security key to a user and assigns the ART Verifier Menu. The verifiers may be clinical pharmacists, dietitians, or other clinical personnel. Automated mail bulletins will be sent to the ART verifiers when an allergy/adverse reaction has been entered and signed (completed) by a user. Verification may be important in observed instances of adverse drug reactions where a Quality Assurance (QA) investigation may be conducted. In general, it is a good principle to have someone verify all of the data entered into ART.

3. Pharmacy and Therapeutics (P&T) Committee users - These users are the members of the hospital's P&T Committee and are assigned the P&T Committee Menu option. They will use the information in ART to review ADRs in the hospital, classify them as significant reactions, and determine whether they are related to particular drugs, and depending on the severity of the ADR, may report it further to the FDA. A printed copy of the form used to report to the Food and Drug Administration (FDA) can be generated by ART. Automated mail bulletins will be sent to the P&T Committee users when an observed drug reaction is entered into the system.

4. Software developers - These users will use the data extract utility (GMRADPT routine) to gather ART data for display within their specific VISTA application.

Orientation

This section of the manual provides general information about conventions used in this manual and for using the Adverse Reaction Tracking (ART) application. It describes conventions for character-based (roll and scroll and List Manager) interfaces and also for the graphic user interface (GUI), as seen through the Computerized Patient Record System (CPRS).

Special Commands, Keys, and Conventions

Character-based Interfaces

For purposes of this manual, when a character is enclosed in quotes (e.g., "^"), you should enter only the character(s), not the quotes.

> NOTE: There is a difference between the letter "O" and the number "0," as well as between the number "1" and the letter "l." The space bar functions as a character key as well as an apparent function key which moves the cursor on the screen.

Special Function Keys modify the operation of the terminal. Whenever a reference is made to the use of a function key, its name will be bracketed with "<" and ">" (e.g., <Enter>; <DEL>).

1. The Shift Key (SHIFT) is the most commonly used key. There frequently is one Shift Key on either side of the keyboard labeled "SHIFT." Some keys are used in conjunction with the <SHIFT> key. To use them, first depress the <SHIFT> key and continue holding it while depressing one of the following:
    a. The At Sign "@" means line deletion and deletes data before a double slash (//) and removes that data from the database. The "@" is generally located on the "2" key. There are exceptions, however.
    b. The Up-arrow "^" is frequently located on the "6" key and is used as follows:
    l) Quit -- by inserting "^", you quits/exits a prompt.
    2) Rapid Out -- by inserting "^^", you are sent to the next level (screen or returns to primary menu). Not all VISTA software has this capability.
    c. The question mark "?" is located next to the lower right <SHIFT> key and is used to request help in understanding the format or obtaining a list from which to make a selection.
    l) "?" -- will produce a listing of possible responses, if available from the computer.
    2) "??" -- will result in a more complete help message, if available from the computer.
2. <CAPS LOCK> maintains the <SHIFT> key in the lock position so that all letter keys display as upper case letters. Unlike the Shift Lock Key on a typewriter, it does not shift any key other than the alphabet keys.
3. In general, the carriage Return or Return key <Enter> is the most frequently used key. It signals the computer that you have finished entering data. Information is held without action until the <Enter> is pressed.
4. <DEL> will backspace and delete one character at a time if <Enter> has not yet been depressed. As each character is removed, the cursor automatically backspaces one position.
5. <NO SCROLL> is used to suspend printing of a listing that is longer than the screen.

Simply depress <NO SCROLL> or (on the WYSE terminal) <HOLD SCREEN> to read the screen display. Depress the key again to resume printing the remainder of the display.

General Computer Usage Instruction

Users of ART send information to and receive information from the computer. The computer acts as an intermediary between you and another user to store, reorganize, calculate, and then recall the information.

This section will assist you in obtaining the desired question(s) from the computer and in responding to screen prompts. It is divided into five parts:

Terminology	Describes some basic programming terminology.
Prompts	Assists you in recognizing the various types of prompts.
Responses	Discusses user responses to prompts.
Data Types	Provides a brief description of data types and the kind of data that can be entered.
Queuing Reports	Describes how to send reports to a printer that will print in the future.

Terminology

Attribute: A specific piece of information about a thing or an entity. Another term for attribute is "element."

Record: A grouping of attributes that relate to a common entity. Every person has a name, age, address, social security number (SSN), and date of birth; each has a value. These field names together with their respective values form a record.

File: A group of records that are of the same type. For example, the record defined in the previous paragraph might be found in a group of similar records in a personnel file.

Prompts

A prompt is a question displayed on the screen by the computer. You respond to the prompt by entering information.

Basic: The basic prompt will display what data is to be entered, followed by a colon. Select the number(s) of the entry(ies) you wish to add/edit: Here the prompt is asking you to enter selections from the listing on the screen. You supply an answer that applies.

Default: The default prompt asks a question and supplies an answer. The answer either reflects the most common response associated with the question or, data (a value) that was previously entered.

Do you really want to Halt? YES//
If < Enter> is pressed, the computer recognizes the "YES" default as the accepted answer, and will halt/stop. Notice the "//" after the "YES." This means that you can change the default answer to something else. In this example, if you entered "NO" after the "//," the system would permit you to continue working on the computer.

Select: The select prompt indicates that an answer is expected from you.
If the computer accepts your answer, the data will be stored and another prompt usually appears. If your answer is not on the accepted list, the terminal will beep and "??" will appear after the original question. The question will then be repeated. If the list within the computer is short, it will be displayed on the screen to help you in making a selection. If a list does not display, enter a "?" for a "help message" to appear on the screen. The message should assist you to respond to the question.

Responses

ART is designed to allow you to enter specific information pertaining to the report in question. As a convention, all user responses in the Adverse Reaction Tracking documentation will be in bold letters so that they are differentiated from screen displays.

There should be no space between the comma and first name in a Patient's Name prompt. The convention used in entering names does not use a space in that position. When doing a look-up on a name, you will be beeped from the computer if a space has been entered between the last and first names. Enter it as:

"LAST NAME,FIRST NAME".

Remember to use HELP when questions arise. Type "?," "??," or "???" after any prompt to get a help message. The help message generally tells you what to do. In some instances, a specific list of possible responses is displayed.

Field names in ART have descriptions associated with them. When you type "??" after the prompt, the description of the attributes will be displayed. This utility acts as a glossary within the programs.

Not all prompts must be answered. When you press < Enter> after the prompt without entering data, no value will be assigned to the attribute. The next prompt is then displayed. An attribute with no value in the data element is called a "NULL."

Data Types

Data is entered and used by a variety of individuals. Therefore, not all data is the same nor is it used for the same purposes. Similarly, not all specific data types perform the same functions. It is important that you understands and recognizes the different types of data associated with Adverse Reaction Tracking.

Free Text: Allows a limited number of any combination of alphabetic characters as well as numbers and punctuation marks. Any meaningful sequence of symbols can be entered.

Date/Time: The name of this data type explains the content. All time related date entries must have a date including a time.
Enter "T-1@3PM" for yesterday at 3 in the afternoon.
"T" is a special character that stands for today's date.
Enter "NOW" for today's date and current time.
You may enter date information in any of the following ways:
JAN 22 1957 or 22 JAN 57 or 1/22/57 or 012257

T (for TODAY), T+l (for TOMORROW), T+2, T+7, etc.
T-l (for YESTERDAY), T-3W (for 3 WEEKS AGO), etc.
N = Now (to enter the current date and time)
If the year is omitted, the computer uses the CURRENT YEAR. Sometimes the system allows you to omit the precise day, as: JAN, 1957

Numeric: A field comprised exclusively of numbers, such as a dollar amount. A list of numbers is a group of numbers separated by commas with ranges of the numbers separated by hyphens (-).
For example, 1-2,5 is a valid entry and would mean that you wanted to select choices 1, 2, and 5. Also, the entry 1,2,5 would mean the same thing.

Computed: A field whose value is computed from values of other attributes. Computed field data does not appear in ART. A computed field cannot be edited. Only fields that determine the value of the computed field can be edited (e.g., age is computed from Date of Birth (DOB)).

Set of Codes: Refers to a short list of values (set when the field was developed) each of which can be identified by a brief code.

Pointer to a File: A field that refers to an entry in another file. This relationship is called a pointer.

Variable Pointer: Similar to a "pointer", except that the relationship is to several files. As an example, there could be a field that chooses either from the GMR Allergies file or the National Drug file for its entry choices.

Word Processing: Similar to free text in that any characters can be entered; however, there is no limit to the amount of text that can be entered. The built-in word processor in the VISTA System is an elemental line-oriented type of system that is easy to use. Help messages are available to you. There are two characteristics of the line editor that may not be obvious. Text will not wrap around; therefore, it is best to track the cursor on the screen and press the Return key to begin a new line. Secondly, while a line of text is being entered, the only editing permitted is through the use of the <DEL> key (to delete characters to the left of the cursor). However, once an entire text is entered, it can be edited with the Replace technique.

Replace Technique:
For example, you enter the following:

```
l>This is an example of how to use thye REPLACE< Enter>
2>technique to edit text entered by you.< Enter>
3>< Enter>
```

After you have entered the text, the system gives you the option to edit the text line by line. Your input is in bold.

```
Edit Option: EDIT line 1 < Enter>
l>This is an example of how to use thye REPLACE
REPLACE thye < Enter> WITH the < Enter>
```

The system returns the corrected piece of text.

```
l>This is an example of how to use the REPLACE
Edit Line: < Enter>
```

Other features of the Replace are:
Type ."‥" at the Replace prompt to replace the entire line of text.
Type "END" at the Replace prompt to append text at the end of the current line of text.

Queuing Reports

When a report must be printed and a user wishes the CRT available for data entry, the desired report can be queued in the following manner:

1. Select a print option from an appropriate display.
2. Enter at Device prompt: Q (QUEUE TO PRINT ON).
3. The Device prompt will again display; you must enter the name of the device.
4. You will also need to set the right margin (e.g., 132 or 80 columns); usually the default is selected.
5. Another prompt "Requested Time to Print" must also be completed before the queuing parameters are completed.

Example:

```
DEVICE: HOME// Q< Enter> QUEUE TO PRINT ON

DEVICE: HOME// (Enter Printer Name; e.g., 132< Enter>)

REQUESTED TIME TO PRINT: NOW// (Select from options listed below)
```

a. Pressing the Return key will print the report immediately if the printer is available.
b. Specific time such as: 10:25AM (NOV 28, 1996 10:25AM).
c. "^" will allow you to exit and the report will not be queued by indicating TRY LATER.

If either (a) or (b) is entered by you, the report will be printed by the appropriate printer device; the CRT can be used concurrently while the report is printing. The computer will display the following message:

Sign On/Sign Off

1. To sign on, you must use the access and verify codes you were assigned. Keep both codes confidential!
   Respond to the prompts:
   ACCESS CODE: First, enter your access code. Then, press the Enter or Return key.
   VERIFY CODE: Enter your verify code. Then, press the Enter or Return key.
   To ensure security, your ACCESS and VERIFY CODES will not be visible on the screen.

2. To SIGN OFF, either:
   a. Press the Return key or,

   b. Enter an up-arrow (^) and then press the Return key until the following prompt appears:
   "Do you really want to halt"? Yes// **< Enter>**

• **Option examples:** Menus and examples of computer dialogue that you see on the CRT screen are depicted here in boxes:

```
Select Enter/Edit Site Configurable Files Option: 2 Enter/Edit
Signs/Symptoms Data
Select a LOCAL SIGN/SYMPTOM: HAIR LOSS
NAME: HAIR LOSS// < Enter>
Select SYNONYM: BALD// < Enter>
Select a LOCAL SIGN/SYMPTOM: < Enter>
```

List Manager Conventions

• **List Manager Screen Display:** The List Manager utility allows ART (and other applications) to maintain the header and action portion of a list, while the center display (for example, the problems or the detailed display) scrolls. So if a patient has too many problems to fit within the scrolling portion of the screen, pressing the return key causes that portion of the screen to scroll up while the top and bottom stay unchanged.

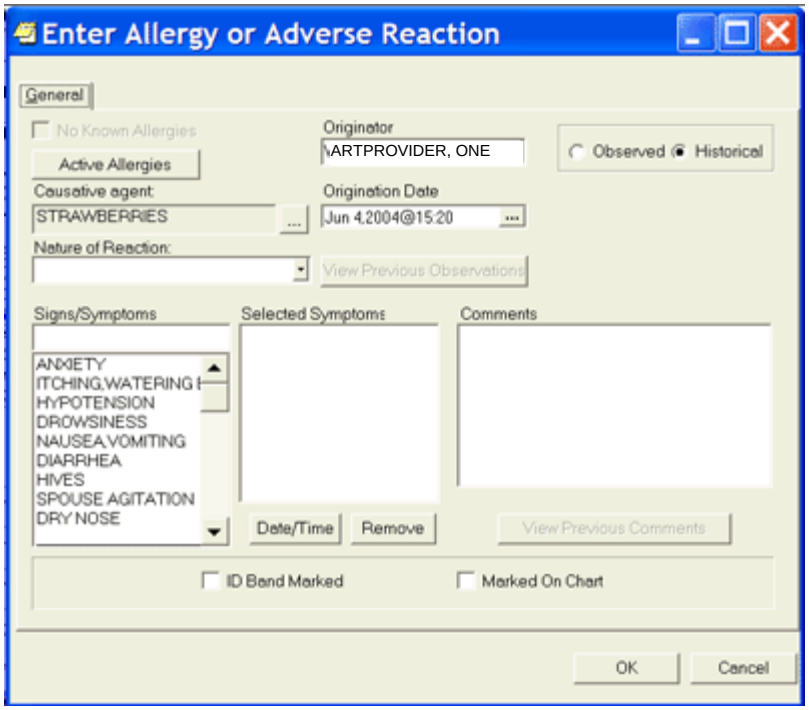
- **CPRS List Manager Capture Examples:**

```
Cover Sheet                    Jun 16, 2004@08:25:27          Page:    1 of    2
ARTPATIENT,ONE            666-66-8828            1A(1&2)              4/19/46(58)
Attend: ARTProvider,one     PrimCare: UNKNOWN     PCTeam:
     Item                                        Entered
     Allergies/Adverse Reactions                |
1    CHOCOLATE (rash)                           | 09/27/00
                                                |
     Patient Postings                           |
     <None>                                     |
                                                |
     Recent Vitals                              |
     Pain:  2                                   | 06/07/00 15:08
                                                |
     Recent Immunizations                       |
                                                |
     Eligibility                                |
     Service Connected 70%                      |
+         Enter the numbers of the items you wish to act on.
NW  Enter New Allergy/ADR CV  (Change View ...)     SP  Select New Patient
AD  Add New Orders        CC  Chart Contents ...    Q   Close Patient Chart

Select: Next Screen// NW   Enter New Allergy/ADR
```

The highlighted bar in the middle contains instructions about actions you can take.

For example:
You can type + to move forward or - to move back. To see a list of navigation actions, type two question marks (??) at the Select Action prompt.

- **CPRS GUI Capture Examples:**
  Examples of ART in CPRS GUI are graphic captures such as the following:



Windows Conventions

See the CPRS online help or the SACC GUI Conventions (available at: http://vista.med.va.gov/sacc/docref.html

Package Management

This package does not impose any additional legal requirements on you, nor does it relieve you of any legal requirements. All users are reminded that many of the reports and mail bulletins generated by this package contain confidential patient information, which is protected by the Privacy Act. A basic knowledge of VISTA is presumed for most users of the software. The Application Coordinator (ADPAC) should have more than a basic knowledge of VISTA and the needs of a clinical environment.

The software does contain two security keys. The GMRA ALLERGY VERIFY key is needed to verify allergy/adverse reactions. The GMRA SUPERVISOR key should be given only to those users who have the authority to override the software's security in order to edit data.

The software itself does not prompt for a user's electronic signature. However, it does contain a programming interface with the Progress Notes package in order to create, edit, and sign progress notes. The Progress Notes software does prompt you for an electronic signature.

The software generates mail bulletins when certain events happen and sends a bulletin to a specified mail group. The mail groups are:

1. GMRA MARK CHART - A list of users who will need to be notified that the ID Band needs to be updated. The new message reads "The ID band for the following patient needs to indicate that the following Allergy/adverse reaction has been reported"

2. GMRA VERIFY DRUG ALLERGY - A list of all verifiers who will need to be sent drug reaction information.

3. GMRA VERIFY FOOD ALLERGY - A list of all verifiers who will need to be sent food reaction information.

4. GMRA VERIFY OTHER ALLERGY - A list of all verifiers who will need to be sent other types of reaction information (i.e., not drug or food).

5. GMRA P&T COMMITTEE FDA - A list of the members of the Pharmacy and Therapeutic (P&T) Committee.

6. GMRA REQUEST NEW REACTANT - When adding a new allergy entry, you are prompted for the reactant. If you cannot find a reactant to match your input, then you are given the option to send an email message requesting that the new reactant be added.

Contact the ADPAC or IRM support staff if you need to be a member of one of these mail groups.

Package Operation

Adverse Reaction Tracking (ART) can be used through CPRS – both the GUI and List manager interfaces, and through GMRA options in character-based VistA. This manual primarily describes the latter use, but also briefly describes the use in CPRS.

Within in character-based VistA, the ART software includes six menus to assist users in tracking and reporting allergy/adverse reaction data:

1. Adverse Reaction Tracking [GMRAMGR] - This is the top-level menu. It should be given to the package's ADPAC and/or IRM support person.

2. Adverse Reaction Tracking User Menu [GMRA USER MENU] - This menu can be assigned to clerks who will enter adverse reaction data.

3. Adverse Reaction Tracking Clinician Menu [GMRA CLINICIAN MENU] - This menu can be assigned to clinicians who will use the package.

4. Adverse Reaction Tracking Verifier Menu [GMRA VERIFIER MENU] - This menu should be assigned to users who will verify adverse reaction data.

5. P&T Committee Menu [GMRA P&T MENU] - This menu can be given to Pharmacy and Therapeutic Committee members.

The rest of this chapter describes the menus and options. Also, examples of each option are given.

Adverse Reaction Tracking

This is the main menu that has all options of the Adverse Reaction Tracking System. This menu should only be given to the ART Applications Coordinator (ADPAC) and/or IRM support personnel.

1. Enter/Edit Site Configurable Files ...
2. Adverse Reaction Tracking User Menu ...
3. Adverse Reaction Tracking Clinician Menu ...
4. Adverse Reaction Tracking Verifier Menu ...
5. P&T Committee Menu ...

Enter/Edit Site Configurable Files

This is a menu of the various options that the site can use to tailor ART to better meet its needs. This menu should be used by the ADPAC or IRM Support Staff only.

1. Edit Allergy File
2. Enter/Edit Signs/Symptoms Data
3. Enter/Edit Site Parameters
4. Sign/Symptoms List
5. Allergies File List
6. Free text allergy clean up utility

Edit Allergy File

This option allows the site to enter its own allergies into the system for selection by you. These entries are considered local entries and can be edited by the site. The software is distributed with a list of entries that is categorized as NATIONAL allergies. The site can edit the SYNONYM field for national entries only. The data is stored in the GMR ALLERGIES file (#120.82).

Example of adding an allergy:

```
Select Enter/Edit Site Configurable Files Option: 1 Edit Allergy File

Select a LOCAL ALLERGY/ADVERSE REACTION: STINKWEED
  Are you adding 'STINKWEED' as a new GMR ALLERGIES (the 117TH)? Y (Yes)
    GMR ALLERGIES ALLERGY TYPE: ??
       This field contains the type(s) for this allergy/adverse reaction. The
       user can enter the type(s) separated by commas, or the following codes:
       D=Drug, F=Food, O=Other. If codes are used, do not use commas to
       separate multiple codes. Examples of valid entries are: DRUG or DRUG,
       FOOD or D or DF or OTHER.
    GMR ALLERGIES ALLERGY TYPE: O
NAME: STINKWEED// <Enter>
Select SYNONYM: WEED
   Are you adding 'WEED' as a new SYNONYM (the 1ST for this GMR ALLERGIES)? Y
    (Yes)
Select SYNONYM: < Enter>
   1 Drug
   2 Food
   3 Other
Select the type(s) for this reaction: 3// <Enter>
Select DRUG INGREDIENT: ?
  Answer with DRUG INGREDIENTS
You may enter a new DRUG INGREDIENTS, if you wish
Enter one of the drug ingredients that make up this allergy.
Answer with DRUG INGREDIENTS NAME
Do you want the entire 3585-Entry DRUG INGREDIENTS List? N (No)
Select DRUG INGREDIENT: <Enter>
Select VA DRUG CLASSES: ?
  Answer with VA DRUG CLASSES
     You may enter a new VA DRUG CLASSES, if you wish
  Answer with VA DRUG CLASS CODE, or CLASSIFICATION
 Do you want the entire 494-Entry VA DRUG CLASS List? N (No)
Select VA DRUG CLASSES: <Enter>

Select a LOCAL ALLERGY/ADVERSE REACTION: <Enter>
```

Example of adding a synonym to a nationally distributed allergy:

```
Select Enter/Edit Site Configurable Files Option: 1 Edit Allergy File
Select a LOCAL ALLERGY/ADVERSE REACTION: CAFFEINE NATIONAL ALLERGY

CANNOT EDIT NAME FIELD OF A NATIONAL ALLERGY.

Select SYNONYM: STIMULANT
  Are you adding 'STIMULANT' as a new SYNONYM (the 1ST for this GMR
ALLERGIES)? Y
(Yes)
Select SYNONYM: <Enter>
Select a Local Allergy/Adverse Reaction: <Enter>
```

Enter/Edit Signs/Symptoms Data

This option allows the addition/editing of the site-specific allergy reactions. The site may find the signs/symptoms list provided by ART inadequate for its needs. This option will allow the site to add any data as appropriate. This data is stored in the Sign/Symptoms file (#120.83).

```
Select Enter/Edit Site Configurable Files Option: 2 Enter/Edit
Signs/Symptoms Data

Select a LOCAL SIGN/SYMPTOM: HAIR LOSS
NAME: HAIR LOSS// <Enter>
Select SYNONYM: BALD// <Enter>

Select a LOCAL SIGN/SYMPTOM: <Enter>
```

Enter/Edit Site Parameters

The Enter/Edit Site Parameters [GMRA SITE FILE] option allows site configuration for multiple divisions at the site. The software provides a generic site configuration entry called HOSPITAL. These parameters are stored in the GMR Allergy Site Parameters file (#120.84).

The site can configure the following:

1. The list of the ten most common signs/symptoms that you will see.

2. The autoverification of data. Autoverification is the process by which the software automatically changes the status of the data to verify when you who entered the data signs off (completes) on it. The site can determine which of the types of reactions are to be autoverified and which are to follow the normal verification procedure. There are three parameters used to autoverify data: Autoverify Food/Drug/Other, Autoverify Observed/Historical, and Autoverify Logical Operator. The verification of data is important. Minimally, all drug reactions will need verification. Depending on the site, food and other allergies may also need to be verified. Users who will verify the data must have the GMRA-ALLERGY VERIFY security key.

3. Whether the originator of the data should provide comments.

4. Whether the site documents the marking of a patient's ID band or chart to indicate the presence of an allergy/adverse reaction. There are three parameters with regards to this documentation: Mark ID Band Flag Method of Notification, Alert ID Band/Chart Mark, and Send Chart Mark Bulletin for New Admissions.

5. FDA reporting data. The site can choose to require you to enter FDA data at the time a reaction is entered. Also, the site may edit the reporter information that will appear on the FDA Adverse Reaction reports.

6. Whether to allow comments to be added to the reaction data that is entered in error. This allows you to indicate why the data is incorrect.

Example:

```
Select Enter/Edit Site Configurable Files Option: 3  Enter/Edit Site Parameters
Select GMR ALLERGY SITE PARAMETERS NAME: ??
   HOSPITAL

         You may enter a new GMR ALLERGY SITE PARAMETERS, if you wish
         This field is the name of this set of parameters.  The name of the base
         set that is sent out is "HOSPITAL".  The code will work more efficiently
         if the name of the base set of parameters is not changed from "HOSPITAL"
.

Select GMR ALLERGY SITE PARAMETERS NAME: HOSPITAL
NAME: HOSPITAL// (No editing)
Select DIVISION: ?
    Answer with DIVISION
   Choose from:
   VAMC ONE
   VAMC TWO
   VAMC THREE
```

```
       You may enter a new DIVISION, if you wish

 Answer with INSTITUTION NAME, or STATUS, or STATION NUMBER, or
     OFFICIAL VA NAME, or CURRENT LOCATION, or CODING SYSTEM/ID PAIR, or
     NAME (CHANGED FROM), or CODING SYSTEM
 Do you want the entire INSTITUTION List? N  (No)
Select DIVISION: VAMC ONE

The following are the ten most common signs/symptoms:
 1. CHILLS                          6. DIARRHEA
 2. ITCHING,WATERING EYES           7. HIVES
 3. HYPOTENSION                     8. DRY MOUTH
 4. DROWSINESS                      9. DRY NOSE
 5. NAUSEA,VOMITING                10. RASH
Enter the number of the sign/symptom that you would like to edit: ??
    ENTER THE CORRECT NUMBER (1-10) OF THE SIGN/SYMPTOM TO BE EDITED
Enter the number of the sign/symptom that you would like to edit: 6
REACTION: DIARRHEA// ??

       One of the ten most commonly selected reactions.


   Choose from:
   AGITATION        NATIONAL SIGN/SYMPTOM
   AGRANULOCYTOSIS        NATIONAL SIGN/SYMPTOM
   ALOPECIA        NATIONAL SIGN/SYMPTOM
   ANAPHYLAXIS        NATIONAL SIGN/SYMPTOM
   ANEMIA        NATIONAL SIGN/SYMPTOM
   ANOREXIA        NATIONAL SIGN/SYMPTOM
   ANXIETY        NATIONAL SIGN/SYMPTOM
   APNEA        NATIONAL SIGN/SYMPTOM
   APPETITE,INCREASED        NATIONAL SIGN/SYMPTOM
   ARRHYTHMIA        NATIONAL SIGN/SYMPTOM
   ASTHENIA        NATIONAL SIGN/SYMPTOM
   ASTHMA        NATIONAL SIGN/SYMPTOM
   ATAXIA        NATIONAL SIGN/SYMPTOM
   ATHETOSIS        NATIONAL SIGN/SYMPTOM
   BRACHYCARDIA        NATIONAL SIGN/SYMPTOM
   BREAST ENGORGEMENT        NATIONAL SIGN/SYMPTOM
   BRONCHOSPASM        NATIONAL SIGN/SYMPTOM
   CARDIAC ARREST        NATIONAL SIGN/SYMPTOM
   CHEST PAIN        NATIONAL SIGN/SYMPTOM
             ^
REACTION: DIARRHEA// AGITATION       NATIONAL SIGN/SYMPTOM

The following are the ten most common signs/symptoms:
 1. CHILLS                          6. AGITATION
 2. ITCHING,WATERING EYES           7. HIVES
 3. HYPOTENSION                     8. DRY MOUTH
 4. DROWSINESS                      9. DRY NOSE
 5. NAUSEA,VOMITING                10. RASH
Enter the number of the sign/symptom that you would like to edit: <Enter>
AUTOVERIFY FOOD/DRUG/OTHER: NO AUTOVERIFY// ??
       This field determines which types of allergies a site wants autoverified
       at you sign off.

     Choose from:
       0        NO AUTOVERIFY
       1        AUTOVERIFY DRUG ONLY
       2        AUTOVERIFY FOOD ONLY
       3        AUTOVERIFY DRUG/FOOD
       4        AUTOVERIFY OTHER ONLY
```

```
       5        AUTOVERIFY DRUG/OTHER
       6        AUTOVERIFY FOOD/OTHER
       7        AUTOVERIFY ALL
AUTOVERIFY FOOD/DRUG/OTHER: NO AUTOVERIFY// <Enter>
AUTOVERIFY OBSERVED/HISTORICAL: NO AUTOVERIFY// ??
        This field is configurable by the site to allow autoverification of
        observed or historical allergies.

     Choose from:
       0        NO AUTOVERIFY
       1        AUTOVERIFY HISTORICAL ONLY
       2        AUTOVERIFY OBSERVED ONLY
       3        AUTOVERIFY BOTH
AUTOVERIFY OBSERVED/HISTORICAL: NO AUTOVERIFY//
AUTOVERIFY LOGICAL OPERATOR: OR// ??
        This field will determine how the Autoverify Food/Drug/Other and
        Autoverify Observed/Historical parameters relate to each other.  OR means
        that the reaction will be autoverified if it meets the criteria of one of
        the two parameters, while AND means the reaction will be autoverified only
        if it meets the criteria of both parameters.  If this field is left null,
        the OR condition will be used.

        For example, if you want to verify only observed drug reactions, you would
        set the Autoverify Food/Drug/Other parameter to AUTOVERIFY FOOD/OTHER
        and the Autoverify Observed/Historical to AUTOVERIFY HISTORICAL ONLY, and the
        Autoverify Logical Operator to OR.  This means that a reaction that has
        a type of Food/Other OR is Historical will be autoverified, thus leaving
        observed drug reactions to be verified.

        Another example would be if you wanted to verify all observed reactions
        and all drug reactions whether observed or historical.  The parameters
        should be set accordingly:  Autoverify Food/Drug/Other to AUTOVERIFY
        FOOD/OTHER, Autoverify Observed/Historical to AUTOVERIFY HISTORICAL ONLY and
        Autoverify Logical Operator to AND.  In this case to be autoverified, a
        reaction has to have a type of Food/Other AND it must be Historical, all
        other reactions will need to be verified.

     Choose from:
       !        OR
       &        AND
AUTOVERIFY LOGICAL OPERATOR: OR// <Enter>
REQUIRE ORIGINATOR COMMENTS: NO// ??
        This field indicates whether the originator will be required to enter
        comments for an OBSERVED reaction.

     Choose from:
       0        NO
       1        YES
REQUIRE ORIGINATOR COMMENTS: NO// <Enter>
MARK ID BAND FLAG: YES// ??
        This field is an indicator to denote whether the site wants
        to document if the patient ID band should be marked for
        a certain allergy.
        The system will assume the site wants to document the marking of inpatient
        ID bands.  If this field is answered NO, the site does not want to
        document the marking of inpatient ID bands.

     Choose from:
       0        NO
       1        YES
MARK ID BAND FLAG: YES// <Enter>
METHOD OF NOTIFICATION: BULLETIN// ??
        This field tells ART if or how users should be notified for chart
```

```
        or ID band markings.  There are three methods. The first method is the
        use of BULLETINs,  which is the current way ART works.  The
        second method is the use of OE/RR Teams.  If this method is used, then
        you will need to set up different teams for each ward and also assign
        printers to these teams.  The third method is to turn off the function.

     Choose from:
       0        BULLETIN
       1        OE/RR TEAMS
       2        NO NOTIFICATION
METHOD OF NOTIFICATION: BULLETIN// <Enter>
ALERT ID BAND/CHART MARK: YES// ??
        This field is to let the system know if you want to issue alerts
        if the fields have not been answered in the Enter/Edit Patient Reaction
        Data portion of the system.  If the field is answered yes(1) or is null
        then, the system will continue to issue the alerts.  If this field is
        no(0), then the system will not issue alerts for this record.

     Choose from:
       1        YES
       0        NO
ALERT ID BAND/CHART MARK: YES// <Enter>
SEND CHART MARK BULLETIN FOR NEW ADMISSIONS: YES// ??
        This is to indicate if the site wants to send chart mark bulletin
        for a new admission.

     Choose from:
       1        YES
       0        NO
SEND CHART MARK BULLETIN FOR NEW ADMISSIONS: YES// <Enter>
FDA DATA REQUIRED: YES// ??
        This field will indicate whether the entry of FDA Data should be required
        during the Enter/Edit Patient Reaction Data.  If this field is answered "YES",
        then you must enter the FDA Data at the time of entering a reaction.
        If this field is left null or answered "NO", then the FDA Data entry will
        not be required during the Enter/Edit Patient Reaction Data option.

     Choose from:
       y        YES
       n        NO
FDA DATA REQUIRED: YES// <Enter>
ENABLE COMMENTS FIELD FOR REACTIONS THAT ARE ENTERED IN ERROR: NO
         // ??
        Permit users to indicate why a reaction was Entered in Error.

     Choose from:
       1        YES
       0        NO
ENABLE COMMENTS FIELD FOR REACTIONS THAT ARE ENTERED IN ERROR: NO
         // <Enter>

REPORTER NAME:
      ADDRESS:
         CITY:
        STATE:
          ZIP:
        PHONE:
   OCCUPATION:
Do you want to edit Reporter Information shown above? No// <Enter>  (No)

   1      Edit Allergy File
   2      Enter/Edit Signs/Symptoms Data
   3      Enter/Edit Site Parameters
```

```
   4      Sign/Symptoms List
   5      Allergies File List
   6      Free text allergy clean up utility

You have PENDING ALERTS
          Enter  "VA to jump to VIEW ALERTS option

Select Enter/Edit Site Configurable Files Option:
```

NOTE: These "Reporter" data fields contain the site's default values that will appear on the FDA adverse reaction reports. This information may be left blank. You will be prompted for the reporter information when creating an FDA report.

Sign/Symptoms List

This option lets you print a list of entries in the Sign/Symptoms file (#120.83). You may print all entries by accepting the default value (FIRST) at the "Name" prompt or may select a subset of entries. The listing includes the name of the sign/symptom, whether it is a nationally distributed entry or a locally created entry, and any of its synonyms. This option is meant to be a useful tool for ADPACs in maintaining the Sign/Symptoms file.

Example:

```
Select Enter/Edit Site Configurable Files Option: 4 Sign/Symptoms List
START WITH NAME: FIRST// <Enter>
DEVICE: (Enter a printer name for a hard copy or <Enter> to bring the
output to your screen)

SIGN/SYMPTOMS LIST                          JUN  8,2004  09:23    PAGE 1
NAME                          Nat'l/Local  SYNONYM
------------------------------------------------------------------------

AGITATION                     National
AGRANULOCYTOSIS               National
ALOPECIA                      National
ANAPHYLAXIS                   National
ANEMIA                        National
ANOREXIA                      National
ANXIETY                       National     ANX
APNEA                         National
APPETITE,INCREASED            National
ARRHYTHMIA                    National
ASTHENIA                      National
ASTHMA                        National
ATAXIA                        National
ATHETOSIS                     National
BRACHYCARDIA                  National
BREAST ENGORGEMENT            National
BRONCHOSPASM                  National
CARDIAC ARREST                National
CHEST PAIN                    National
CHILLS                        National
COMA                          National
CONFUSION                     National
CONGESTION,NASAL              National
CONJUNCTIVAL CONGESTION       National
CONSTIPATION                  National
COUGHING                      National
DEAFNESS                      National
DELERIUM                      National
DELUSION                      National
DEPRESSION                    National
DEPRESSION,MENTAL             National
DEPRESSION,POSTICTAL          National
...
```

Allergies File List

This option prints a captioned list of all entries in the GMR Allergies file (#120.82). The list is sorted alphabetically by NAME. You may list all entries by accepting the default answer (FIRST) to the "start with" prompt or may select a subset to print. The list contains the allergy name, type, whether it is a nationally distributed entry, synonyms, if any, VA Drug Class, if applicable, and drug ingredients, if applicable. This option is meant to be a helpful tool for maintaining the GMR Allergies file.

Example

```
Select Enter/Edit Site Configurable Files Option: 5 Allergies File List
START WITH NAME: FIRST// <ret>
DEVICE: (Enter a printer name for a hard copy or <ret> to bring the output to
your screen)

GMR ALLERGIES LIST                                JUN  8,2004  09:20    PAGE 1
-------------------------------------------------------------------------------

NAME: ADHESIVE TAPE                          ALLERGY TYPE: OTHER
  NATIONAL ALLERGY: NATIONAL ALLERGY

NAME: ALCOHOL                                ALLERGY TYPE: DRUG, FOOD
  NATIONAL ALLERGY: NATIONAL ALLERGY
DRUG INGREDIENT: ALCOHOL

NAME: ANIMAL HAIR                            ALLERGY TYPE: OTHER
  NATIONAL ALLERGY: NATIONAL ALLERGY

NAME: ANISE OIL                              ALLERGY TYPE: DRUG, FOOD
  NATIONAL ALLERGY: NATIONAL ALLERGY
DRUG INGREDIENT: ANISE OIL

NAME: ANTIRABIES SERUM                       ALLERGY TYPE: DRUG, FOOD
  NATIONAL ALLERGY: NATIONAL ALLERGY
VA DRUG CLASSES: IM400
DRUG INGREDIENT: ANTIRABIES SERUM

NAME: ASCORBIC ACID                          ALLERGY TYPE: DRUG, FOOD
  NATIONAL ALLERGY: NATIONAL ALLERGY
VA DRUG CLASSES: VT400
DRUG INGREDIENT: ASCORBIC ACID

NAME: ASPARTAME                              ALLERGY TYPE: DRUG, FOOD
  NATIONAL ALLERGY: NATIONAL ALLERGY
SYNONYM: NUTRA SWEET
DRUG INGREDIENT: ASPARTAME

NAME: ASPIRIN                                ALLERGY TYPE: DRUG, FOOD
  NATIONAL ALLERGY: NATIONAL ALLERGY
VA DRUG CLASSES: MS101
DRUG INGREDIENT: ASPIRIN
...
```

Free Text Allergy Clean Up Utility

This option was distributed with Patch GMRA*4.0*17 to help sites identify and fix allergy entries that have free-text reactants.

After installing this patch, free-text entries are no longer allowed from within the ART package. A subsequent patch (OR*3*216) to CPRS prevents free-text entries from within CPRS as well.

Lower-case entries are also no longer allowed. Previously, lower-case entries could be added to the GMR ALLERGIES file (120.82). A patch 17 post-installation routine identified any local entries and updated the entries to upper case. Synonyms were also be checked and converted to upper case, if required.

A new mail group, GMRA REQUEST NEW REACTANT, was added with this patch. Sites should populate this mail group with the people responsible for addressing requests to add new reactants. If users attempt to enter a reactant that is not found during the look-up process, they are asked if they would like to send an email requesting the addition of the new reactant. The request can then be reviewed for accuracy and new local entries can be added, if appropriate. Previously, users were asked if they wanted to add the new entry and it was immediately available in the patient's record. Under the new system, the new reactant must be reviewed before it is added to the patient's record.

When you start the utility, a list of currently existing free-text entries is displayed in alphabetical order. This list may take a few minutes to generate, as all existing entries need to be evaluated to determine which ones are "free text." The list shows the name of the reactant and the number of entries for that reactant. In most cases, they will be unique, but there will be some that have many entries (such as an entry for NO KNOWN ALLERGIES).

When entering the utility, any users who are currently working in the utility are listed. If users are listed as working with the utility, you will not be allowed to update the list. You can only update the list when nobody else is working in the utility.

Once the list is displayed, you can do three things:

1. Mark the entry as entered in error
2. Update it so that it points to an existing reactant (hopefully, the one that it should have been pointed to originally).
3. Add new reactants to the GMR ALLERGIES file (120.82) as local entries, if they are not found in any existing files.

```
Select OPTION NAME: GMRA SITE FILE MENU     Enter/Edit Site Configurable Files
menu

   1      Edit Allergy File
   2      Enter/Edit Signs/Symptoms Data
   3      Enter/Edit Site Parameters
   4      Sign/Symptoms List
   5      Allergies File List
   6      Free text allergy clean up utility

You have PENDING ALERTS
          Enter  "VA to jump to VIEW ALERTS option

Select Enter/Edit Site Configurable Files Option: 6
Free text allergy clean up utility



Building list of free text allergies...this may take a few minutes


Allergy Tracking Update       Oct 27, 2003@08:17:58          Page:    1 of    1
Allergy Tracking Free Text Entries
    Reactant                                  # Active Entries
1   CEFAZOLIN SOD 1GM INJ                            1
2   Diabetes Mellitus Type II                        1
4   Penicillin                                       1
5   WATERMELON                                       3

          Select one or more entries
AE  Add/Edit Allergy File EE  Mark entered in error
DD  Detailed Display      UR  Update to new reactant
Select Item(s): Quit// ??

Use AE to add local allergies to the GMR ALLERGY file.  This
should only be done if you're sure no existing reactant matches your needs.

Use EE to mark all entries within the selected group as entered
in error.  You may select multiple groups if you like.

Use DD to get a detailed display.  It's highly recommended that you
use the detailed display menu to make all changes.

Use UR to update the reactant.  Extreme caution should be used when doing
mass updates.  It would be better to do the updates from within
the detailed display menu.

Press enter to continue:
```

NOTE: When you start the utility, you may see 3 different things: 1) If the list has never been built, you'll see the message below (building list…), 2) If the list has been previously built and nobody is using the utility, you'll see a message indicating the last time the list was built and you will be asked if you'd like to rebuild the list, 3) If the list is currently being built, you'll get a message indicating that you must wait. Most times a user will see the message in number 2.

Detailed Display

The detailed display window shows the patient name and the list of currently active allergies, separated by a tilde (~). This way, you can quickly look and see if the patient already has an active allergy that is the same as the free-text entry. In this case, you would mark it as entered in error.

The "free text detailed display" action lets you see a FileMan inquiry-style listing of the free text entry for selected patient(s). You'll now be able to see the comments, reactions, and other associated information for the free text entry that you're fixing.

When doing a group update or selecting multiple patients for updating from the detailed display listing, the reactant you select for the first patient in the list will become the default for the remaining patients. The exception to that would be if you decide to not accept the default while updating one of the patients. In that case, the last chosen reactant will become the default for the next patient. The default only holds while working with a particular group. Once you select a new reactant group or a new group of patients, you must re-select the reactant. This should cut down on the amount of time needed in selecting the reactant for each patient.

1. Select the Free text allergy clean up utility [GMRA FREE TEXT UTILITY] from the GMRA SITE FILE MENU.

2. Select the number of a reactant first, and then select DD to see details about the reactant. (Alternatively, you can select the action, DD, and then select the number of the reactant.)

NOTE: For detailed display, you can only select one group at a time.

```
GMRA SITE FILE MENU     Enter/Edit Site Configurable Files menu

   1      Edit Allergy File
   2      Enter/Edit Signs/Symptoms Data
   3      Enter/Edit Site Parameters
   4      Sign/Symptoms List
   5      Allergies File List
   6      Free text allergy clean up utility

You have PENDING ALERTS
          Enter  "VA to jump to VIEW ALERTS option

Select Enter/Edit Site Configurable Files Option: 6  Free text allergy clean up
utility

Building list of free text allergies...this may take a few minutes

Allergy Tracking Update       Oct 24, 2003@15:09:28          Page:    1 of    1
Allergy Tracking Free Text Entries
     Reactant                                    # Active Entries
1    COCA COLA SYRUP 8OZ                                1
2    Diabetes Mellitus Type II                          1
3    NO ALLERGIES                                       1
4    NO KNOWN ALLERGIES                                 1
5    Penicillin                                         1
6    PIZZA                                              1
7    POLLEN ANTIGEN MIX                                 1

+         Select one or more entries
AE  Add/Edit Allergy File EE  Mark entered in error
DD  Detailed Display      UR  Update to new reactant
Select Item(s): Next Screen// 3
```

```
Allergy Tracking Update       Oct 24, 2003@15:09:28          Page:    1 of    1
Allergy Tracking Free Text Entries
     Reactant                                    # Active Entries
1    COCA COLA SYRUP 8OZ                                1
2    Diabetes Mellitus Type II                          1
3    NO ALLERGIES                                       1
4    NO KNOWN ALLERGIES                                 1
5    Penicillin                                         1
6    PIZZA                                              1
7    POLLEN ANTIGEN MIX                                 1

+         Select one or more entries
AE  Add/Edit Allergy File EE  Mark entered in error
DD  Detailed Display      UR  Update to new reactant

Select Item(s): Next Screen// DD   Detailed Display
```

```
Reactant Detailed Display     Oct 24, 2003@15:09:28          Page:    1 of    1
Patient listing for reactant CEFAZOLIN SOD 1GM INJ
    Patient Name                    Last 4
1   ARTPATIENT,ONE                    0111
Allergies: PENICILLIN VK ORAL SOLUTION~AMIKACIN~PEANUT OIL~CORTISONE~NUTS~DUST~
   STRAWBERRIES~CHICKEN~CHOCOLATE~PHENOL~HAYFEBROL SF~ASA~BILE SALTS~
   BILBERRY EXTRACT~POLLEN~POLLEN ALLERGENIC EXTRACT~
   ANTIHEMOPHILIC FACTOR,HUMAN~CEFAZOLIN SOD 1GM INJ~SHELL FISH~
   RANITIDINE


          Select a patient
EE  Entered in Error                      PR  Add/Edit Patient Reaction
UR  Update to new reactant                DD  Free Text Detailed Display
AE  Add/Edit Allergy File
Select Item(s): Quit// DD   Free Text Detailed Display
Select Entries from list: 1

PATIENT: ARTPATIENT,ONE                     REACTANT: CEFAZOLIN SOD 1GM INJ
  GMR ALLERGY: OTHER ALLERGY/ADVERSE REACTION
  ORIGINATION DATE/TIME: OCT 02, 2003@14:02
  ORIGINATOR: ARTPROVIDER,ONE             OBSERVED/HISTORICAL: HISTORICAL
  ORIGINATOR SIGN OFF: YES                NATURE OF REACTION: UNKNOWN
  VERIFIED: NO                            ALLERGY TYPE: DRUG

Press return to continue or '^' to stop: <Enter>
```

Mark Entered in Error

You can mark an entire group as entered in error from this opening screen. Upon marking the reaction as entered in error, a check is made to see if there are still active reactions for the patient. If there are not any, then you are prompted to enter an updated assessment for the patient.

1. Select the Free text allergy clean up utility [GMRA FREE TEXT UTILITY] from the GMRA SITE FILE MENU.

2. Select the number of the reactant(s) you wish to mark as entered in error. (Alternatively, you can select the action, Mark Entered in Error, and then select the number of the reactant(s).)

```
Select Enter/Edit Site Configurable Files Option: 6  Free text allergy clean up
utility

Building list of free text allergies...this may take a few minutes

Allergy Tracking Update   Sep 19, 2003@11:18:04            Page:    1 of    4
Allergy Tracking Free Text Entries
    Reactant                                  # Active Entries

1   COCA COLA SYRUP 8OZ                             1
2   COLD AIR                                        1
3   Diabetes Mellitus Type II                       1
4   DOG HAIR                                        1
5   DONUTS                                          1
6   DOUGH                                           1
7   DR P'S SNAKE OIL ELIXIR                         1
8   DRUGS                                           1
9   EIEIO                                           1
10  ENCAINIDE 25MG                                  1


          Select one or more entries
AE  Add/Edit Allergy File EE  Mark entered in error
DD  Detailed Display      UR  Update to new reactant
Select Item(s): Quit// 5
```

3. Type EE for Mark entered in error, and then answer Yes to confirm that you want to mark ALL allergies as entered in error.

```
Select Item(s): Next Screen// EE   Mark entered in error

You are about to mark ALL allergies with the selected reactant
as entered in error.

ARE YOU SURE? NO// Yes
```

Update to New Reactant

You may select and update groups of entries from the opening menu; however, it is recommended that you use the detailed display option to review entries in a group before doing a mass update. ***Changes cannot be undone***! When the entry is updated, a comment is stored in the PATIENT ALLERGY file indicating who made the change, date/time of change, and a comment that indicates what the previous value was and what the new value is. In addition, the new reactant is compared against current orders and order checking information is returned, if appropriate. When a new reactant is selected, checks are made for duplicate entries and previously entered-in-error information.

NOTE: Due to the way the order checking software works, you may get "false positives." In other words, if the patient currently has an allergy order check for some other order not related to this new reactant, you may still see the order check.

Finally, the drug ingredient/drug class information is updated, if appropriate.

1. Select the Free text allergy clean up utility [GMRA FREE TEXT UTILITY] from the GMRA SITE FILE MENU.

2. Select a reactant number and then select the action DD.

```
Select Enter/Edit Site Configurable Files Option: 6  Free text allergy clean up
utility

Building list of free text allergies...this may take a few minutes

Allergy Tracking Update       Oct 27, 2003@08:35:56          Page:    1 of    1
Allergy Tracking Free Text Entries
    Reactant                                  # Active Entries
1   CEFAZOLIN SOD 1GM INJ                            1
2   Diabetes Mellitus Type II                        1
3   NO ALLERGIES                                     1
4   NO KNOWN ALLERGIES                               1
5   Penicillin                                       1
6   WATERMELON                                       3

          Select one or more entries
AE  Add/Edit Allergy File EE  Mark entered in error
DD  Detailed Display      UR  Update to new reactant
Select Item(s): Quit// 6
```

```
Allergy Tracking Update       Oct 27, 2003@08:36:38          Page:    1 of    1
Allergy Tracking Free Text Entries
    Reactant                                    # Active Entries
1   CEFAZOLIN SOD 1GM INJ                              1
2   Diabetes Mellitus Type II                          1
3   NO ALLERGIES                                       1
4   NO KNOWN ALLERGIES                                 1
5   Penicillin                                         1
6   WATERMELON                                         3


+         Select one or more entries
AE  Add/Edit Allergy File EE  Mark entered in error
DD  Detailed Display      UR  Update to new reactant
Select Item(s): Quit// dd   Detailed Display

Reactant Detailed Display     Oct 27, 2003@08:25:50          Page:    1 of    1
Patient listing for reactant WATERMELON
    Patient Name                    Last 4
1   ARTPATIENT,ONE                    0111
Allergies: WATERMELON
2   ARTPATIENT,TWO                    0222
Allergies: WATERMELON
3   ARTPATIENT,THREE                  0333
Allergies: ASPIRIN~WATERMELON

+         Select one or more entries
EE  Entered in Error                      PR  Add/Edit Patient Reaction
UR  Update to new reactant                DD  Free Text Detailed Display
AE  Add/Edit Allergy File
Select Item(s): Quit// 1
```

3. Select an item # in the Detailed Display, then select UR for Update to New Reactant.

```
Reactant Detailed Display     Oct 27, 2003@08:40:29          Page:    1 of    1
Patient listing for reactant WATERMELON
    Patient Name                    Last 4
1   ARTPATIENT,ONE                  0111
Allergies: WATERMELON
2   ARTPATIENT,TWO                  0222
Allergies: WATERMELON
3   ARTPATIENT,THREE                XXXX
Allergies: ASPIRIN~WATERMELON


          Select a patient                                              >>>
EE  Entered in Error                      PR  Add/Edit Patient Reaction
UR  Update to new reactant                DD  Free Text Detailed Display
AE  Add/Edit Allergy File
Select Item(s): Quit// ur   Update to new reactant

You are about to update the selected patient's
WATERMELON allergy to a new reactant.

ARE YOU SURE? NO// YES
For patient ARTPATIENT,ONE

Enter Causative Agent: ONION

Checking GMR ALLERGIES (#120.82) file for matches...

Now checking INGREDIENT (#50.416) file for matches...
```

```
 EXTRACT
         ...OK? Yes//<ENTER>   (Yes)


You selected ONION EXTRACT
Is this correct? Y// <ENTER> ES
Performing order checking...No problems found
Press enter to continue: <ENTER>
```

```
Reactant Detailed Display     Oct 27, 2003@08:44:13          Page:    1 of    1
Patient listing for reactant WATERMELON
    Patient Name                        Last 4
1   ARTPATIENT,ONE                      0111
Allergies: WATERMELON
2   ARTPATIENT, TWO                     0222
Allergies: ASPIRIN~WATERMELON

          Select a patient                                              >>>
EE  Entered in Error                      PR  Add/Edit Patient Reaction
UR  Update to new reactant                DD  Free Text Detailed Display
AE  Add/Edit Allergy File
Select Item(s): Quit//
```

Add/Edit Patient Reaction

This action allows you to add/edit patient reactions. This allows reviewers using the utility to add a new reaction if you receive a free-text reaction such as MORPHINE, PENICILLIN. When you correct this type of entry, you can only make it be one or the other.

```
Reactant Detailed Display     Sep 19, 2003@13:05:28          Page:    1 of    1
Patient listing for reactant DIABETES MELLITUS TYPE II
    Patient Name                       Last 4
1   ARTPATIENT,ONE                      0111
Allergies: AMOXICILLIN~ASPIRIN~MILK~ERYTHROMYCIN~CHROMA-PAK INJECTION~
   Diabetes Mellitus Type II~PENICILLINS
```

```
          Select a patient
EE  Entered in Error                    PR  Add/Edit Patient Reaction
UR  Update to new reactant              DD  Free Text Detailed Display
AE  Add/Edit Allergy File
Select Item(s): Quit// PR   Add/Edit Patient Reaction

You should use this option to add NEW reactions only.  If you mark
existing free text entries as entered in error from within this option it will
not update the utility's display until the list is rebuilt upon re-entry
of this option.  This could cause confusion as the list will no longer
be accurate.

Press enter to continue: <Enter>

Select PATIENT NAME:    ARTPATIENT,ONE       2-22-42    666-11-0111     YES
ACTIVE DUTY
 Enrollment Priority:            Category: IN PROCESS    End Date:



                                                                  OBS/
REACTANT                                              VER.   MECH.   HIST  TYPE
--------                                              ----  -------  ----  ----
ALUMINUM ACETATE                                      AUTO  UNKNOWN  HIST  DRUG
    Reactions: CHILLS
AMOXICILLIN                                            NO   UNKNOWN  HIST  DRUG
AMPICILLIN                                             NO   UNKNOWN  HIST  DRUG
CARAMEL                                               YES   ALLERGY  HIST  DRUG
    Reactions: HIVES, ITCHING,WATERING EYES
CN900                                                 YES   ALLERGY  HIST  DRUG
 (AMITRIPTYLINE, PERPHENAZINE)
    Reactions: ITCHING,WATERING EYES, ANXIETY,
               DRY MOUTH
HAYFEBROL SF                                           NO   UNKNOWN  HIST  DRUG
 (CALCIUM PHOSPHATE, CELLULOSE, CHLORPHENIRAMINE,
  MAGNESIUM STEARATE, POVIDONE, PSEUDOEPHEDRINE,
  SODIUM STARCH GLYCOLATE)
    Reactions: ITCHING,WATERING EYES
LOMEFLOXACIN                                          YES   UNKNOWN  OBS   DRUG
    Reactions: ITCHING,WATERING EYES
PENICILLINS                                            NO   UNKNOWN  HIST  DRUG

Press RETURN to continue or '^' to stop listing:
```

```
                                                                OBS/
REACTANT                                          VER.   MECH.  HIST  TYPE
--------                                          ----   -------  ----  ----
PENTAMIDINE                                       YES    ALLERGY  HIST  DRUG
PENTAZOCINE                                       YES    ALLERGY  HIST  DRUG
RANITIDINE                                        AUTO   UNKNOWN  OBS   DRUG
 (CITRIC ACID, SODIUM CHLORIDE, SODIUM PHOSPHATE)
    Reactions: CHILLS
TAPE                                               NO    UNKNOWN  HIST  DRUG
TAVIST                                             NO    UNKNOWN  HIST  DRUG
 (CLEMASTINE)
TAVIST                                             NO    UNKNOWN  HIST  DRUG
 (CLEMASTINE)
CHOCOLATE                                         YES    UNKNOWN  HIST  DRUG
 (CHOCOLATE FLAVORING)                                                  FOOD
FISH                                               NO    UNKNOWN        DRUG
 (FISH LIVER OIL)                                                       FOOD
FLUPHENAZINE DECANOATE                             NO    UNKNOWN  HIST  DRUG
                                                                        FOOD
PEANUT OIL                                         NO    UNKNOWN  OBS   DRUG
    Reactions: ITCHING,WATERING EYES, ANXIETY                           FOOD

Press RETURN to continue or '^' to stop listing:


                                                                OBS/
REACTANT                                          VER.   MECH.  HIST  TYPE
--------                                          ----   -------  ----  ----
NUTS                                              YES    ALLERGY  HIST  FOOD
    Reactions: HIVES
STRAWBERRIES                                      YES    UNKNOWN  HIST  FOOD
DUST                                              YES    UNKNOWN  HIST  OTHER

Enter Causative Agent:
```

Add/Edit Allergy File

The final thing that you can do with the utility is to add a new local allergy, if no good choices exist. This is the last resort and should only be used if no other possibility exists. However, due to regional variances, etc., there might be a need to add a local allergy. Once entered, this allergy will then be available for assignment to currently existing free-text entries

1. Select the Free text allergy clean up utility, to start the ART Clean-up Utility.

2. Select AE, Add/Edit Allergy File.

```
Select Enter/Edit Site Configurable Files Option: 6  Free text allergy clean up
utility

Building list of free text allergies...this may take a few minutes

Allergy Tracking Update       Sep 19, 2003@13:05:28         Page:    1 of    4
Allergy Tracking Free Text Entries
    Reactant                                    # Active Entries
1   COCA COLA SYRUP 8OZ                                1
2   COLD AIR                                           1
3   Diabetes Mellitus Type II                          1
4   DOG HAIR                                           1
5   DONUTS                                             1
6   DOUGH                                              1
7   DR P'S SNAKE OIL ELIXIR                            1
8   DRUGS                                              1
9   EIEIO                                              1
10  ENCAINIDE 25MG                                     1

+         Enter ?? for more actions
AE  Add/Edit Allergy File EE  Mark entered in error
DD  Detailed Display      UR  Update to new reactant
Select Item(s): Next Screen// AE   Add/Edit Allergy File

Select a LOCAL ALLERGY/ADVERSE REACTION: DANDER
  Are you adding 'DANDER' as a new GMR ALLERGIES (the 112TH)? No// Y  (Yes)
   GMR ALLERGIES ALLERGY TYPE: ?
     Answer with type(s) of this reaction.  E.g., FOOD or DRUG, FOOD or F or
     DF.
   GMR ALLERGIES ALLERGY TYPE: ???
        This field contains the type(s) for this allergy/adverse reaction .  The
        user can enter the type(s) separated by commas, or the following codes:
        D=Drug, F=Food, O=Other.  If codes are used, do not use commas to
        separate multiple codes.  Examples of valid entries are:  DRUG or DRUG,
        FOOD or D or DF or OTHER.

   GMR ALLERGIES ALLERGY TYPE: O
NAME: DANDER// <Enter>
Select SYNONYM:
  1   Drug
  2   Food
  3   Other
Select Classification(s) of Causative Agent: 3// <Enter>
Select DRUG INGREDIENT: ??

     You may enter a new DRUG INGREDIENTS, if you wish
     This is one of the drug ingredients that make up this causative agent.
```

```
   Choose from:
   1,1,1 TRICHLOROETHANE
   2-AMINO-2-METHYL-1-PROPANOL
   2-PHENYLBENZIMIDAZOLE-5-SULFONIC ACID
   4-DILAURATE
   ABACAVIR SULFATE
   ABCIXIMAB
   ABSORPTION BASE
   ACACIA
   ACACIA POWDER
   ACARBOSE
   ACEBUTOLOL
   ACEBUTOLOL HYDROCHLORIDE
   ACEMANNAN
   ACETAMIDE MEA
   ACETAMINOPHEN
   ACETANILIDE
   ACETATE
   ACETAZOLAMIDE
   ACETAZOLAMIDE SODIUM
               ^
Select DRUG INGREDIENT: <Enter>
Select VA DRUG CLASSES: ?
        You may enter a new VA DRUG CLASSES, if you wish

 Answer with VA DRUG CLASS CODE, or CLASSIFICATION
 Do you want the entire 573-Entry VA DRUG CLASS List? N  (No)
Select VA DRUG CLASSES: <Enter>
```

Signing off on Allergies

Before patch 17, the allergy tracking package allowed users to leave entries in a "not signed off" state. Although not complete, the allergy became part of the patient's record, even though you were told that it would not be. Depending on how the entry was made, an alert might not be sent indicating that the entry needed to be signed off. Ultimately, an unfinished entry might never be finished, but still appear in the patient's record.

A change has been made so that no new entry can be left in a "not signed off" state. Upon entering a new allergy, if you enters an "^" at any point during the data gathering process, the entry will be deleted. Upon completing the new entry, you will be asked if the entry is okay. If you enter no, then they'll be given the opportunity to edit or delete the entry. The entry must then be deleted or accepted before exiting this process. As a result, no new entries will be allowed to be in an unsigned state.

NOTE: Sites should run the "Patient Allergies Not Signed Off" option to identify all existing entries that have not yet been completed. Each entry should be reviewed and marked as entered-in-error or completed by entering the required information. Once these entries are cleaned up, then no unsigned entries should appear in the patient's chart. You are not required to update these entries as data may not be available but you should review them and take action if possible. The post-installation routine will also list any allergies that are observed, have been signed off, but are missing either an observed date or a sign/symptom. These entries should also be reviewed and updated if possible.

```
GMRA CLINICIAN MENU     Adverse Reaction Tracking Clinician Menu

   1      Enter/Edit Patient Reaction Data
   2      FDA Enter/Edit Menu ...
   3      Reports Menu ...
   4      Edit Chart and ID Band
   5      Online Reference Card

You have PENDING ALERTS
          Enter  "VA to jump to VIEW ALERTS option

Select Adverse Reaction Tracking Clinician Menu Option: 3  Reports Menu

   1      Active Listing of Patient Reactions
   2      Print Patient Reaction Data
   3      Print an FDA Report for a Patient
   4      List by Location of Unmarked ID Bands/Charts
   5      Patient Allergies Not Signed Off
   6      List by Location of Undocumented Allergies
   7      List by Location Not Verified Reactions
   8      List by Location and Date All Signed Reactions
   9      List FDA Data by Report Date


You have PENDING ALERTS
          Enter  "VA to jump to VIEW ALERTS option

Select Reports Menu Option: 5  Patient Allergies Not Signed Off

DEVICE: HOME//   ANYWHERE
```

```
                ALLERGY/ADVERSE REACTIONS TO BE SIGNED OFF
                    Run Date/Time: 9/30/03 12:12:09 pm

ORIGINATOR              PATIENT            ALLERGY        ORIGINATION DATE/TIME
--------------------------------------------------------------------------------



       NO DATA FOR THIS REPORT
Enter RETURN to continue or '^' to exit:
```

GMRA*4*19 Notifications from CPRS when allergies are added

With this patch, a couple of issues related to the utility that was released in patch GMRA*4*17 will be addressed. In addition, the sending of bulletins related to new allergy entry, need for verification, and need for marking chart/ID bands will now be done when entering an allergy from CPRS GUI.

This patch also changes the order in which files that contain matching reactants appear to you. With patch GMRA*4*17, the names of the files that contained matching selections were displayed before the list of matches. Although this helps identify the file from which you're choosing, users will still often pick the first match that they see.

Selections from the ingredient and drug class file, while legitimate, only supply partial information that is required for order checking to work. As a result, the ingredient and drug class files were moved to the bottom of the selection list to encourage selection from one of the drug-related files or the GMR ALLERGIES file (#120.82), which will provide complete information.

Q&A Tips:

Q: What do you do with an entry like number 1?

A: This entry actually has multiple reactants listed and you need to make sure you account for each of the reactants that are listed. We recommend that you go to the detailed display for the entry in question and then use the add/edit patient reaction option to add the extra reactants and then to update the entry to the first reactant listed.

Q: Do I need to fix every entry that's listed?

A: That would be the goal but the truth is, if you can't figure out what it should be linked to, or if the entry as it exists in the patient allergy file has all of the drug class and drug ingredient information, you can leave it alone. It's better to have information available that you may not be sure is correct and be wrong than to get rid of the information and have it be correct.

Q: We have a problem with No Known Allergies type entries.

A: If you're one of the sites that added NKA as a local allergy, it won't appear in this list. If you haven't already done so, you need to check your GMR Allergies file to see if there is an entry for NKA or something similar.

NOTE: With GMRA*4.0*21, it is now possible to delete an assessment of NKA from within the ART package.

When you select a patient for entering/editing allergies and that patient doesn't have any active allergies on file, the “Does this patient have any known allergies or adverse reactions?” prompt is presented to you. If the patient has no assessment, there is no default answer. If the patient has been assessed as NKA, the default is NO.

In the case where the default answer is NO (meaning, the patient is NKA), you may enter an @ sign to indicate that the assessment should be deleted and the patient should be returned to the 'not assessed' state. This would be used in those rare cases where an assessment is erroneously assigned to the wrong patient.

Adverse Reaction Tracking User Menu

This menu is assigned to all users of Adverse Reaction Tracking who are not clinicians, verifiers, or ADP coordinators. The options on this menu allow you to enter, edit, and display allergy/adverse reaction data.

1. Enter/Edit Patient Reaction Data
2. Active Listing of Patient Reactions
3. Edit Chart and ID Band
4. List by Location of Unmarked ID Bands/Charts
5. Patient Allergies Not Signed Off
6. List by Location of Undocumented Allergies
7. Print Patient Reaction Data

8 Online Reference Card

Enter/Edit Patient Reaction Data

This option allows users to enter and edit patient allergies/adverse reactions. You are prompted to enter the name of the agent that caused the reaction, whether the reaction was observed during the patient's stay/visit at the facility, any signs/symptoms associated with the reaction, the date and time the sign/symptom occurred, the type of reaction (i.e., mechanism), any appropriate comments concerning the entry, and whether the patient's ID band is marked for this reaction.

Selecting a Patient:

You may select a patient by name (last name, first name), full Social Security Number (SSN), the last four digits of the SSN (e.g., 1234), the first letter of the last name and last four digits of the SSN (e.g., A1234), or ward location (e.g., 1 North).

Does the patient have any known allergies/adverse reactions?

If the selected patient does not have any allergies/adverse reactions stored in the ART database, you are asked the above question. A Yes response will allow you to make an entry. A No response will take you back to the patient prompt. If the ART database contains allergy/adverse reaction information about the patient, the software will not ask this question, but will instead display information about the existing reactions. The software will display the name of the causative agent, the type of causative agent (e.g., food), any signs/symptoms, its mechanism (e.g., Allergy or Pharmacologic), whether it was an observed reaction or historical, and whether or not it was verified.

Selecting a Causative Agent:

The lookup procedure that is performed when you enter a causative agent deserves a detailed explanation.

1) If the causative agent exists as an entry for the patient, then you have the opportunity to edit the data concerning that entry.

2) If your response is not part of that patient's entry or you do not want to edit an existing choice given in Step 1, then a lookup for the particular agent is done using six files of choices, which are searched in the following order:

    1. GMR Allergies (#120.82) - this file is distributed with the ART software and contains nationally distributed food and other type agents plus any entries added locally by the facility,
    2. National Drug (#50.6) - this file contains the names of available drug products including trade names and manufacturer, and
    3. National Drug File - Trade Names (#50.67)
    4. Drug (#50) - this file contains the names of drugs that can be used to fill a prescription.
    5. Drug Ingredients (#50.416) - this file contains the names of individual generic drugs which are components of various drug products,
    6. VA Drug Class (#50.605) - this file contains the names of the various drug classes used within the Department,

3) If your reactant is not found after Steps 1 and 2, then you are asked “Would you like to send an email requesting (the reactant) be added as a causative agent?” If you answer NO you will return to the reactant lookup; if you answer yes, you see the message “You may now add any comments you may have to the message that is going to be sent with the request to add this reactant. You may want to add things like sign/symptoms, observed or historical, etc that may be useful to the reviewer.

Enter RETURN to continue or '^' to exit: “ If enter is pressed, then the user is allowed to enter comments, and when the comments are saved, the user gets the message “Message sent - NOTE: This reactant was NOT added for this patient.

Enter another Causative Agent? YES//” If the user answers YES, they return to the reactant lookup prompt; if they answer NO, they return to the patient lookup prompt. A mail message is generated to the User making the request and to the Mail Group GMRA REQUEST NEW REACTANT containing the comment entered, the user and contact information, patient, and the reactant.

NOTE: If a particular causative agent is commonly selected, but it comes from a lookup on one of the later files (i.e., 2b, 2c, 2d or 2e) and the facility wishes to minimize the response lookup time, then that causative agent can be added to the GMR Allergies file as a local entry. Since this is the first file that is looked up in Step 2, the response time will be reduced.

NOTE: When selecting entries from the Drug file (#50) you may see the various dosages associated with the drugs. You only need to pick one of these dose forms. The software will figure out which ingredients from that drug the patient had a reaction to and set that information into the database automatically.

Observed vs. Historical Reaction:

An observed reaction is an event that actually happened to the patient during the patient’s stay/visit at the facility. A historical reaction is one that is reported, but not observed by the facility personnel. If the reaction is observed you will be asked to enter the observation date. The time of day may be entered, but it is optional.

Observed Report:

For an observed reaction, you are asked for additional information. You may enter the name of the person who observed the reaction (the default response is the name of you entering the data), the severity of the reaction (i.e., mild, moderate or severe), and the date a medical doctor was notified. Also, you may edit the date and time of the observation. You will only see these prompts if he/she has the GMRA-ALLERGY VERIFY KEY.

Signs/Symptoms:

A sign/symptom is an effect of the reaction on the patient (e.g., itching). The software comes with a list of nationally recognized signs/symptoms. The site can add additional signs/symptoms to the list. The software displays to you a list of commonly reported signs/symptoms to choose from. You may choose from this abbreviated list or from the full list of choices. You may select as many signs/symptoms as applicable. The site may customize the abbreviated list you see to meet its needs. Observed reactions require you to enter signs/symptoms. A historical reaction allows,

but does not require you to enter signs/symptoms.

Free text sign/symptoms are allowed.

Also, you are asked to enter the date the sign/symptom appeared. The time of day may be entered, but it is optional.

Mechanism:

The mechanism is the type of reaction. The choices are Allergy, Pharmacologic, or Unknown. An allergic reaction occurs because the patient is sensitive to a causative agent regardless of the amount the patient is exposed to. A pharmacologic (non-allergic) reaction occurs when the patient is sensitive to an agent under certain conditions such as exposure to a large amount. Unknown is provided if you are not sure what mechanism to enter. You will only see these prompts if he/she has the GMRA-ALLERGY

NOTE: Allergies are a subset of the world of adverse reactions. All allergies are adverse reactions, but not all adverse reactions are allergies.

Comments:
The site can determine whether comments from the originator of the entry are required, by setting a software parameter. If that site parameter is set to YES, you are required to enter comments concerning the entry. If the entry is being edited and any existing comments exist for this causative agent, the software will display those comments and whether they were entered by the originator of the entry, a verifier, or a person who marked the entry as entered in error.

FDA Data:

When the type of the causative agent is a drug, you may enter further information about the reaction, which will be used by the software to generate an FDA report. The questions for the FDA report are categorized in four sections. Users are encouraged to provide as much information about the reaction as possible. The site can determine if you will be required to enter FDA data by setting a software parameter. You will only see these prompts if you have the GMRA-ALLERGY VERIFY KEY.

Verification of Data:

Entries can be verified by a user or by the software. The latter is known as autoverification. The site can determine how the entries are verified by setting three software parameters. The combination of these three parameters allows the software to automatically verify none, some, or all entries. Conversely, sites may wish to have their users verify none, some, or all entries. If the entry must be verified by a user and the user has the verification key, GMRAALLERGY VERIFY, the software will allow the verification of the data during the enter/edit option. The user has an opportunity to review and edit the data before verifying the entry.

Generating Progress Notes:

The ART software has an interface to the TIU package. A progress note will be generated when you verify or enter an observed drug reaction, or mark an entry as entered in error. Also, you may print the note. You will only see these prompts if you have the GMRA-ALLERGY VERIFY KEY.

Signing Off on an Entry:

Signing off (i.e., is the data correct?) on an entry means the user who entered/edited the entry is satisfied with the data entered. It does not mean an electronic signature. Users who have the verification key will not be asked to sign off on an entry if they verify it.

Users who have the verification key will be asked to sign off on an entry if they do not verify it. Users who do not have the verification key will be asked to sign off on the entry.

```
Select Adverse Reaction Tracking User Menu Option: 1 Enter/Edit Patient
Reaction Data
Select PATIENT NAME: ARTPATIENT,ONE 04-01-23 666110111 SC VETERAN

OBS/REACTANT                                    VER.  MECH.    HIST  TYPE
--------                                        ----  ----     ----  ----
ASPIRIN                                         AUTO  ALLERGY HIST  DRUG
   Reactions: CHILLS, DRY MOUTH, CHEST PAIN
DILANTIN                                        YES   ALLERGY OBS   DRUG
 (PHENYTOIN)
   Reactions: DROWSINESS
IBUPROFEN                                        NO    UNKNOWN OBS   DRUG
  PENICILLIN                                     YES   UNKNOWN OBS   DRUG
   Reactions: HIVES, DROWSINESS
PHENOBARBITAL                                    YES   ALLERGY OBS   DRUG
   Reactions: DEPRESSION
TETRACYCLINE                                     YES   PHARM   OBS   DRUG
   Reactions: DROWSINESS
Enter Causative Agent: CHEESE
Checking existing PATIENT ALLERGIES (#120.8) file for matches...

Now checking GMR ALLERGIES (#120.82) file for matches...

   CHEESE   OK? Yes//   (Yes)

(O)bserved or (H)istorical Allergy/Adverse Reaction: O OBSERVED

Select date reaction was OBSERVED (Time Optional):  t  (DEC 06, 2004)   DEC
06,
2004  (DEC 06, 2004)
  Are you adding 'DEC 06, 2004' as
    a new ADVERSE REACTION REPORTING? No// y  (Yes)


No signs/symptoms have been specified.  Please add some now.

The following are the top ten most common signs/symptoms:
 1. CHILLS                          7. HIVES
 2. ITCHING,WATERING EYES           8. DRY MOUTH
 3. HYPOTENSION                     9. DRY NOSE
 4. DROWSINESS                     10. RASH
 5. NAUSEA,VOMITING                11. OTHER SIGN/SYMPTOM
 6. DIARRHEA
Enter from the list above :  10
Date(Time Optional) of appearance of Sign/Symptom(s): Dec 06, 2004//  (DEC 06,
2004)


The following is the list of reported signs/symptoms for this reaction:
```

```
     Signs/Symptoms                                          Date Observed
-------------------------------------------------------------------------------
  1  RASH                                                    Dec 06, 2004

Select Action (A)DD, (D)ELETE OR <RET>:



COMMENTS:
  1>
Complete the observed reaction report? Yes//   (Yes)
DATE/TIME OF EVENT: DEC 6,2004//
OBSERVER: CPRSPROVIDER,EIGHT     BCC          Chief Medical Officer
SEVERITY: m
     1   MILD
     2   MODERATE
Choose 1-2: 1  MILD
DATE MD NOTIFIED: Dec 6,2004//   (DEC 06, 2004)
Enter another Causative Agent? YES// n  NO



                              Dec 06, 2004@14:02:53
Causative Agent Data edited this Session:
ADVERSE REACTION
----------------
  CHEESE

           Obs/Hist: OBSERVED
            Obs d/t: Dec 06, 2004
     Signs/Symptoms: RASH (12/6/04)Is this correct? NO// y YES
```

Active Listing of Patient Reactions

This option will give a brief listing of the active (i.e., data that is signed off and not entered in error) allergy/adverse reaction data for a selected patient. You may select a printer to get a hard copy printout, or display the report to the terminal screen.

The header of the display contains the report name, date and time it was run, patient's name, SSN, date of birth, and age. The body of the report divides the data by reaction type (e.g., Drug) and lists the causative agent, the signs/symptoms, and when they were observed or if they were historical, and whether it was verified.

If the patient has no known reactions, the body of the report will display that the patient has no known allergies. If the patient was never asked if he/she has any allergy/adverse reactions, the body of the report will display a message stating that there are no reactions on file.

```
Select PATIENT: ARTPATIENT,ONE 04-01-23 666110111     YES     ACTIVE DUTY
 Enrollment Priority:            Category: IN PROCESS    End Date:

DEVICE: HOME// ;;999  ANYWHERE


                   ACTIVE ALLERGY/ADVERSE REACTION LISTING
                     Run Date/Time: 6/25/04 11:56:58 am
ARTPATIENT,ONE          666-11-0000             FEB 22,1942 (62)

                                                                        OBS/
 ADVERSE REACTION                                          VERIFIED     HIST
-------------------------------------------------------------------------------


   TYPE: DRUG
   ==========
ALLENT                                                     YES          HIST
ALUMINUM ACETATE                                           YES          HIST
     Reactions: CHILLS (Nov 25, 2002)
AMOXICILLIN                                                NO           HIST
AMPICILLIN                                                 NO           HIST
BILBERRY                                                   YES          HIST
CANDESARTAN                                                YES          HIST
CARAMEL                                                    YES          HIST
     Reactions: HIVES (Jan 22, 1998),
                ITCHING,WATERING EYES (Jan 22, 1998)
CORICIDIN TAB                                              YES          OBS
     Reactions: CHILLS, HYPOTENSION, NAUSEA,VOMITING
CORN STARCH                                                YES          HIST
CORRECTOL                                                  YES          HIST
CORTICOTROPIN                                              YES          HIST
CORTICOTROPIN/ZINC HYDROXIDE                               YES          HIST
EYE WASHES/LUBRICANTS                                      NO           OBS
     Reactions: DROWSINESS
FILGRASTIM                                                 YES          HIST
HAYFEBROL SF                                               NO           HIST
     Reactions: ITCHING,WATERING EYES
LOMEFLOXACIN                                               YES          OBS
     Reactions: ITCHING,WATERING EYES (Mar 10, 1999)
OXYCODONE                                                  YES          HIST
PENICILLINS                                                NO           HIST
```

```
PENTAMIDINE                                                    YES       HIST
PENTAZOCINE                                                    YES       HIST
PENTETIC ACID                                                  YES       HIST
RANITIDINE                                                     YES       OBS
     Reactions: CHILLS (Nov 26, 2002@11:16)
TACRINE                                                        YES       HIST
TAPE                                                           YES       HIST
TAVIST                                                         NO        HIST
TAVIST                                                         NO        HIST
WARFARIN                                                       YES       HIST
WATER                                                          NO        HIST
ZANTAC                                                         YES       HIST

   TYPE: DRUG, FOOD
   ================
CHOCOLATE                                                      YES       HIST
FLUPHENAZINE DECANOATE                                         NO        HIST
PEANUT OIL                                                     NO        OBS
     Reactions:
                ITCHING,WATERING EYES (Oct 05, 2000@24:00),
                ANXIETY (Oct 06, 2000@09:27)
SHELL FISH                                                     NO        HIST

   TYPE: FOOD
   ==========
NUTS                                                           YES       HIST
     Reactions: HIVES (Jan 02, 1998)
PEACHES                                                        YES       HIST
STRAWBERRIES                                                   YES       HIST

   TYPE: OTHER
   ===========
DUST                                                           YES       HIST
Enter RETURN to continue or '^' to exit:
```

Edit Chart and ID Band

This option allows you to indicate if the patient ID band or the chart has been marked. It should be used by the personnel charged with the responsibility of making sure that the patient's paper chart has been marked to indicate that an allergy/adverse reaction is present. You select a patient and the various causative agents associated with that patient are displayed. Any number of agents may be selected to indicate whether the patient chart has been marked.

```
Select Adverse Reaction Tracking User Menu Option: 3 Edit Chart and ID Band
Select Patient: ARTPATIENT,TWO        10-04-69  666110222 SC VETERAN
CHOOSE FROM:
   ASPIRIN
   COD LIVER OIL
   DEMECARIUM
   FROGS
   PENBUTOLOL
   PENICILLIN
   PHENOBARBITAL
   PHENYTOIN
   PREDNISONE
   THOR - PROM
   TIMOLOL
   TYLOXAPOL

Select CAUSATIVE AGENT: ASPIRIN 10-04-69 666110222  SC VETERAN
ASPIRIN

Select another CAUSATIVE AGENT: PENICILLIN 10-04-69 666110222
SC VETERAN PENICILLIN

Select another CAUSATIVE AGENT: < Enter>
This session you have CHOSEN:
PENICILLIN
ASPIRIN

Have the Chart(s) been marked for these CAUSATIVE AGENTS? ??
ANSWER YES IF THE Chart(s) HAS BEEN MARKED, ELSE ANSWER NO.
Have the Chart(s) been marked for these CAUSATIVE AGENTS? Y (Yes)
```

List by Location of Unmarked ID Bands/Charts

This option will produce a list of all patients by ward/clinic who have not had their chart or ID bands marked. This report functions like the List of Patients Not Asked About Allergies option. It should be noted that you will be prompted to queue all reports except when choosing the Current Inpatients report by itself (i.e., #1).

The header of the report contains the date the report was run, title of the report, the list of the groups included (i.e., inpatients), and any date ranges entered by you. The body of the report categorizes the patients by clinic or ward. It lists the patient's name, SSN, name of the causative agent, and whether the patient ID band, patient chart, or both were unmarked.

```
Select Adverse Reaction Tracking User Menu Option: 4 List by Location
of Unmarked ID Bands/Charts
      1 Current Inpatients
      2 Outpatients over Date/Time range
      3 New Admissions over Date/Time range
      4 All of the above
Enter the number(s) for those groups to be used in this report: (1-4):
4
 Enter date/time range in which patients were
 admitted into the hospital or seen at an outpatient clinic.

Enter START Date (time optional): T-90 (MAR 30, 2004)
Enter END Date (time optional): T// < Enter> (JUN 28, 2004)
```

The location prompt allows you to select the ward or clinic that you want to print, or select all the wards/clinics by entering the word ALL, and the system will select all the appropriate hospital locations.

```
Select Location: ?

    You may deselect from the list by typing a '-' followed by location
    name.
    E.g. -3E would delete 3E from the list of locations already
    selected.
    You may enter the word ALL to select all appropriate locations.
Answer with HOSPITAL LOCATION NAME, or ABBREVIATION
Choose from:
   1N
   1S
   GMC DR. PETIT
   PHYSICAL EXAM

Select Location: 1N
Another Location: < Enter>

QUEUE TO PRINT ON
DEVICE: SELECT APPROPRIATE PRINTER

Requested Start Time: NOW// <Enter> (JUN 28 2004@13:42:26)
Request queued...
Ju 28, 2004 PATIENTS WITH UNMARKED ID BAND/CHART PAGE 1
```

```
Jun 28,2004           PATIENTS WITH UNMARKED ID BAND/CHART           PAGE 1
               CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
                      FROM Mar 30,2004     TO Jun 28,2004@24:00

PATIENT                        SSN            ALLERGY              UNMARKED
--------------------------------------------------------------------------------

          WARD: 1A(1&2)
ARTPATIENT,ONE                 666-11-0111    DAVE DRUG            ID BAND/CHART
                                              DUST                 ID BAND/CHART
                                              AMPICILLIN           ID BAND/CHART
                                              ASPIRIN              ID BAND/CHART
                                              CHOCOLATE            ID BAND/CHART
                                              MILK OF MAGNESIA     ID BAND/CHART
                                              AMOXICILLIN          ID BAND/CHART
                                              PENICILLIN           ID BAND/CHART
                                              MENTHOL              ID BAND/CHART
ARTPATIENT,TWO                 666-11-0222    AMOXICILLIN          ID BAND/CHART
                                              DUST                 ID BAND/CHART
                                              ZANTAC               ID BAND/CHART
ARTPATIENT,THREE               666-11-0333    CEPHALEXIN TABLETS,  ID BAND/CHART
Enter RETURN to continue or '^' to exit:

Jun 28,2004           PATIENTS WITH UNMARKED ID BAND/CHART           PAGE 2
               CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
                      FROM Mar 30,2004     TO Jun 28,2004@24:00

PATIENT                        SSN            ALLERGY              UNMARKED
--------------------------------------------------------------------------------
                                              CHEESE               ID BAND/CHART
                                              BARIUM SULFATE       ID BAND/CHART
                                              OPIOID ANALGESICS    ID BAND/CHART
                                              RADIOLOGICAL/CONTRAS ID BAND/CHART
                                              FOLIC ACID           ID BAND/CHART
                                              STRAWBERRIES         ID BAND/CHART
                                              PENICILLIN           ID BAND/CHART
un 28,2004          PATIENTS WITH UNMARKED ID BAND/CHART              PAGE 3
               CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
                      FROM Mar 30,2004     TO Jun 28,2004@24:00

PATIENT                        SSN            ALLERGY              UNMARKED
--------------------------------------------------------------------------------
                                              ACETANILIDE          ID BAND/CHART
                                              ANTIRABIES SERUM     ID BAND/CHART
ARTPATIENT,FOUR                666-11-0444    STRAWBERRIES         ID BAND/CHART
ARTPATIENT,FIVE                666-11-0555    CHOCOLATE            ID BAND/CHART
                                              BLUE CROSS AMPICILLI ID BAND/CHART
                                              ACETAMINOPHEN TAB    ID BAND/CHART
                                              STRAWBERRIES         ID BAND/CHART
Enter RETURN to continue or '^' to exit:
```

Patient Allergies Not Signed Off

This option prints allergy/adverse reactions for patients who have not been signed off (completed) by the user entering data. Users who have the GMRA-ALLERGY VERIFY key will see all reactions that are not signed off. Users who do not have that key will see just the entries that they created. You may select a printer to get a hard copy printout or display the report to the terminal screen.

The header of the report contains the name of the report and the date and time that it was run. The body of the report lists the name of the person who entered the date, the patient's name followed by the last four digits of the SSN, the causative agent, and the date/time the entry was made.

```
Select Adverse Reaction Tracking User Menu Option: 5 Patient Allergies
Not Signed Off
Include deceased patients on report? NO//

DEVICE: HOME// < Enter> HYPER SPACE
                 ALLERGY/ADVERSE REACTIONS TO BE SIGNED OFF
                      Run Date/Time: 6/28/04 9:18:26 am

ORIGINATOR              PATIENT            ALLERGY        ORIGINATION
DATE/TIME
------------------------------------------------------------------------
PROVIDER,ONE ARTPATIENT,ONE  (0111) PENICILLIN FEB 18, 2003@10:59
PROVIDER,ONE ARTPATIENT,ONE  (0111) FROG FEB 18, 2003@15:14
PROVIDER,ONE ARTPATIENT,ONE  (0111) THORAZINE 10MG FEB 22, 2003@13:20
PROVIDER,ONE ARTPATIENT,TWO  (0112) PENICILLIN JUN 22, 2003@11:44
PROVIDER,ONE ARTPATIENT,TWO  (0112) PHENYTOIN JUN 22, 2003@11:48
PROVIDER,ONE ARTPATIENT,TWO  (0112) DEMECARIUM JUN 22, 2003@12:00
PROVIDER,ONE ARTPATIENT,TWO  (0112) ASPIRIN JUN 22, 2003@12:08
PROVIDER,ONE ARTPATIENT,TWO  (0112) PHENOBARBITAL JUN 25, 2003@10:33
PROVIDER,ONE ARTPATIENT,TWO  (0112) PHENOBARBITAL JUN 25, 2003@10:39
PROVIDER,ONE ARTPATIENT,TWO  (0112) CODEINE JUN 30, 2003@08:55
PROVIDER,ONE ARTPATIENT,TWO  (0112) THOR - PROM AUG 11, 2003@10:35
PROVIDER,ONE ARTPATIENT,TWO  (0112) IMMUNE GLOBULIN AUG 18, 2003@10:02
PROVIDER,ONE ARTPATIENT,THREE (0113)  CYCLOBENZAPRINE JUL 11, 2004@14:11
PROVIDER,ONE ARTPATIENT,THREE (0113)  SULFABENZAMIDE/S JUL 11, 2004@14:14
PROVIDER,ONE ARTPATIENT,THREE (0114)  DUCK JAN 06, 2004@11:13
Enter  RETURN to continue or '^' to exit: ^
```

List by Location of Undocumented Allergies

This report is used to list all patients in the patient database who have never been asked if they have any known allergies. It should be noted that you will be prompted to queue all reports except stand-alone Current Inpatients' reports. The header of the report contains the date the report was run, title of the report, the list of the groups included (i.e., current inpatients), and any date ranges entered by you. The body of the report categorizes the patients by clinic or ward. It lists the patient's name, SSN, and provider. The room-bed will appear for current inpatients.

```
Select Adverse Reaction Tracking User Menu Option: 6 List by Location of
Undocumented Allergies
       1 Current Inpatients
       2 Outpatients over Date/Time range
       3 New Admissions over Date/Time range
       4 All of the above
Enter the number(s) for those groups to be used in this report:(1-4): 4
 Enter date/time range in which patients were
 admitted into the hospital or seen at an outpatient clinic.

Enter START Date (time optional): T-180 (JAN 04, 2004)
Enter END Date (time optional): T// <Enter> (JUL 02, 2004)
```

The location prompt allows you to select the ward or clinic that you want to print, or select all the wards/clinics by entering the word ALL, and the system will select all the appropriate hospital locations.

```
Select Location: ??

    You may deselect from the list by typing a '-' followed by location name.
    E.g. -3E would delete 3E from the list of locations already selected.
    You may enter the word ALL to select all appropriate locations.
 Answer with HOSPITAL LOCATION NAME, or ABBREVIATION
Choose from:
  Choose from:
   1 CARY'S CLINIC
   13A PSYCH
   1A(1&2)
   2B MED
   8E REHAB MED
   8W SUBSTANCE ABUSE
   CARDIOLOGY
   CT ROOM

Select Location: 1A
Another Location: 2B
Another Location: Cardiology
Another Location: < Enter>

QUEUE TO PRINT ON
DEVICE: SELECT APPROPRIATE PRINTER

Requested Start Time: NOW// < Enter> (JUL 2, 2004@10:24:00)
Request queued...
```

```
Jul 2,2004             PATIENTS NOT ASKED ABOUT ALLERGIES            PAGE 1
               CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
                       FROM Jan 4,2004    TO Jul 2,2004@24:00

PATIENT                         SSN            PROVIDER
------------------------------------------------------------------------------

         WARD: 1A(1&2)
ARTPATIENT,ONE             666-00-0111    ARTPROVIDER,ONE
ARTPATIENT,TWO             666-00-1112P
ARTPATIENT,TWO             666-00-1112
                                          ARTPROVIDER,TWO
     Room/Bed: B-2
ARTPATIENT,THREE           666-12-4443    ARTPROVIDER,THREE
     Room/Bed: 9-B
ARTPATIENT,FOUR            666-00-1114
ARTPATIENT,FIVE            666-00-1115
Enter RETURN to continue or '^' to exit:

Jul 2,2004             PATIENTS NOT ASKED ABOUT ALLERGIES            PAGE 2
               CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
                       FROM Jan 4,2004    TO Jul 2,2004@24:00

PATIENT                         SSN            PROVIDER
------------------------------------------------------------------------------

         WARD: 2B MED
ARTPATIENT,SIX             666-00-1116    ARTPROVIDER,FOUR
ARTPATIENT,SEVEN           666-00-1117
Enter RETURN to continue or '^' to exit:


Jul 2,2004             PATIENTS NOT ASKED ABOUT ALLERGIES            PAGE 3
               CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
                       FROM Jan 4,2004    TO Jul 2,2004@24:00

PATIENT                         SSN
------------------------------------------------------------------------------

         CLINIC: CARDIOLOGY
ARTPATIENT,EIGHT           666-00-1118        ARTPROVIDER,FIVE
ARTPATIENT,NINE            666-00-1119
ARTPATIENT,TEN             666-00-1110
Enter RETURN to continue or '^' to exit:
```

If you select a ward/clinic location where no patients meet the report's criteria (i.e., all patients were asked about allergies), then an appropriate message will appear (No Patients for this Ward).

Print Patient Reaction Data

This option will allow you to get a captioned data display of all of the patient's allergy/adverse reaction data. You can send the report to a printer for a hard copy printout or have it displayed on the terminal screen.

You can select the types of reactions to include in the report. Any combination of types can be selected (i.e., FOOD and DRUG). You then select the status of the reaction entry. Any combination can be selected (i.e., ACTIVE and ENTERED IN ERROR).

The header of the report contains the title of the report, the date/time it was run, and the patient's name, SSN, date of birth, and age. The body contains the status of the reaction, its type, the name of the causative agent, any drug ingredients, any VA drug classes, the name of the person who entered the data, and the date and time it was entered. It also contains whether or not the data was signed off (completed), whether the reaction was observed or historical, whether the patient ID band or chart is marked, a list of the signs/symptoms, and additional comments made by the originator. A line of dots appears in the body of the report between the various reaction entries.

```
Select Adverse Reaction Tracking User Menu Option: 7 Print Patient Reaction
Data

Select PATIENT: ARTPATIENT,ONE 10-12-69 666000111 SC VETERAN
Select 1:DRUG, 2:FOOD, 3:OTHER
Type of allergy: (1-3): 1
Select 1:ACTIVE, 2:ENTERED IN ERROR
Which would you like to see?: (1-2): 1

DEVICE: HOME// < Enter> HYPER SPACE

                    ALLERGY/ADVERSE REACTION REPORTS
                     Run Date/Time: 7/2/04 9:18:55 am
ARTPATIENT,ONE          666-00-0111             FEB 22,1942 (62)
------------------------------------------------------------------------------

STATUS: ACTIVE
--------------
  TYPE: DRUG
  ==========

         AGENT: ALLENT
   INGREDIENTS: PSEUDOEPHEDRINE          VA DRUG CLASSES: ANTIHISTAMINE/DECONGE
                BROMPHENIRAMINE

    ORIGINATOR: CRPROVIDER,ONE                 ORIGINATED: MAR 17, 2004@14:34
      SIGN OFF: YES                             OBS/HIST: HISTORICAL

ID BAND MARKED:                              CHART MARKED: MAR 17, 2004@14:34:16


     MECHANISM: ALLERGY

Enter RETURN to continue or '^' to exit:


                     ALLERGY/ADVERSE REACTION REPORTS
                     Run Date/Time: 7/2/04 9:18:55 am
ARTPATIENT,ONE          666-00-0111             FEB 22,1942 (62)
```

```
--------------------------------------------------------------------------------

      VERIFIER: AUTOVERIFIED                    VERIFIED: MAR 17, 2004@14:34:17

.....................................................................
         AGENT: ALUMINUM ACETATE
   INGREDIENTS: ALUMINUM ACETATE         VA DRUG CLASSES:

    ORIGINATOR: ARTPROVIDER,ONE                 ORIGINATED: NOV 26, 2002@11:25
      SIGN OFF: YES                             OBS/HIST: HISTORICAL

ID BAND MARKED:                              CHART MARKED:

SIGNS/SYMPTOMS: CHILLS  (Nov 25, 2002)

     MECHANISM: UNKNOWN

      VERIFIER: AUTOVERIFIED                    VERIFIED: NOV 26, 2002@11:26:27
Enter RETURN to continue or '^' to exit:


                    ALLERGY/ADVERSE REACTION REPORTS
                    Run Date/Time: 7/2/04 9:18:55 am
ARTPATIENT,ONE          666-00-0111             FEB 22,1942 (62)
--------------------------------------------------------------------------------


.....................................................................
         AGENT: AMOXICILLIN
   INGREDIENTS: AMOXICILLIN              VA DRUG CLASSES: PENICILLINS,AMINO DER

    ORIGINATOR: ARTPROVIDER,TWO                 ORIGINATED: JAN 21, 1998@10:20
      SIGN OFF: YES                             OBS/HIST: HISTORICAL

ID BAND MARKED:                              CHART MARKED:


     MECHANISM: UNKNOWN

.....................................................................
         AGENT: AMPICILLIN
   INGREDIENTS: AMPICILLIN               VA DRUG CLASSES:

Enter RETURN to continue or '^' to exit:


                    ALLERGY/ADVERSE REACTION REPORTS
                    Run Date/Time: 7/2/04 9:18:55 am
ARTPATIENT,ONE          666-00-0111             FEB 22,1942 (62)
--------------------------------------------------------------------------------

    ORIGINATOR: ARTPROVIDER,ONE                 ORIGINATED: JAN 21, 1998@10:25
      SIGN OFF: YES                             OBS/HIST: HISTORICAL

ID BAND MARKED:                              CHART MARKED:


     MECHANISM: UNKNOWN
```

Adverse Reaction Tracking Clinician Menu

This menu is assigned to all clinicians of Adverse Reaction Tracking who are not verifiers or ADP coordinators. The options on this menu allow users to enter, edit, and display allergy data, enter Food and Drug Administration report data, run various reports of importance to the clinician, and edit the patient's chart and identification band.

This menu should only be given to the clinicians of ART. This option contains the following options:

1. Enter/Edit Patient Reaction Data
2. FDA Enter/Edit Menu ...
3. Reports Menu ...
4. Edit Chart and ID Band
5. Online Reference Card

Enter/Edit Patient Reaction Data

This option allows users to enter and edit patient allergies/adverse reactions. You are prompted to enter the name of the agent that caused the reaction, whether the reaction was observed during the patient's stay/visit at the facility, any signs/symptoms associated with the reaction, the date and time the sign/symptom occurred, the type of reaction (i.e., mechanism), any appropriate comments concerning the entry, and whether the patient's chart is marked for this reaction.

See Page 40 for descriptions of the prompts for this option. Enter/Edit Patient Reaction Data

Example

```
Select Adverse Reaction Tracking Clinician Menu Option: 1  Enter/Edit Patient Re
action Data

Select PATIENT NAME: CPRSPATIENT,TWO        2-22-42    666324321     YES
ACTIVE DUTY
 Enrollment Priority:           Category: NOT ENROLLED  End Date: 07/06/2004

                                                                    OBS/
REACTANT                                              VER.   MECH.   HIST  TYPE
--------                                              ----  -------  ----  ----
ACE INHIBITORS                                         NO   UNKNOWN  HIST  DRUG
ALLENT                                                AUTO  ALLERGY  HIST  DRUG
 (BROMPHENIRAMINE, PSEUDOEPHEDRINE)
ALUMINUM ACETATE                                      AUTO  UNKNOWN  HIST  DRUG
    Reactions: CHILLS
AMOXICILLIN                                           YES   UNKNOWN  HIST  DRUG
AMPICILLIN                                            YES   UNKNOWN  HIST  DRUG
BILBERRY                                              AUTO  UNKNOWN  HIST  DRUG
 (BILBERRY EXTRACT)
CANDESARTAN                                           AUTO  ALLERGY  HIST  DRUG
CARAMEL                                               YES   ALLERGY  HIST  DRUG
    Reactions: HIVES, ITCHING,WATERING EYES
CORICIDIN TAB                                         AUTO  ALLERGY  OBS   DRUG
    Reactions: CHILLS, HYPOTENSION, NAUSEA,VOMITING
CORN STARCH                                           AUTO  ALLERGY  HIST  DRUG
 (CORN OIL)
CORRECTOL                                             AUTO  ALLERGY  HIST  DRUG
CORTICOTROPIN                                         AUTO  PHARM    HIST  DRUG

Press RETURN to continue or '^' to stop listing: ^

Enter Causative Agent: cheese

Checking existing PATIENT ALLERGIES (#120.8) file for matches...


Now checking GMR ALLERGIES (#120.82) file for matches...

   CHEESE   OK? Yes// <Enter>  (Yes)


(O)bserved or (H)istorical Allergy/Adverse Reaction: o  OBSERVED
Select date reaction was OBSERVED (Time Optional):  t  (DEC 06, 2004)   DEC 06,
2004  (DEC 06, 2004)
  Are you adding 'DEC 06, 2004' as
    a new ADVERSE REACTION REPORTING? No// y  (Yes)
```

```
No signs/symptoms have been specified.  Please add some now.

The following are the top ten most common signs/symptoms:
 1. CHILLS                          7. HIVES
 2. ITCHING,WATERING EYES           8. DRY MOUTH
 3. HYPOTENSION                     9. DRY NOSE
 4. DROWSINESS                     10. RASH
 5. NAUSEA,VOMITING                11. OTHER SIGN/SYMPTOM
 6. DIARRHEA
Enter from the list above :  10
Date(Time Optional) of appearance of Sign/Symptom(s): Dec 06, 2004//<Enter>  (DEC 06,
2004)


The following is the list of reported signs/symptoms for this reaction:

     Signs/Symptoms                                    Date Observed
-------------------------------------------------------------------------------
  1  RASH                                              Dec 06, 2004

Select Action (A)DD, (D)ELETE OR <RET>: <RET>



COMMENTS:
  1>
Complete the observed reaction report? Yes//  <RET> (Yes)
DATE/TIME OF EVENT: DEC 6,2004//
OBSERVER:  CPRSPROVIDER,EIGHT     BCC          Chief Medical Officer
SEVERITY: m
     1   MILD
     2   MODERATE
Choose 1-2: 1  MILD
DATE MD NOTIFIED: Dec 6,2004// <Enter>  (DEC 06, 2004)
Enter another Causative Agent? YES// n  NO



                             Dec 06, 2004@14:02:53
Causative Agent Data edited this Session:
ADVERSE REACTION
----------------
  CHEESE

          Obs/Hist: OBSERVED
           Obs d/t: Dec 06, 2004
    Signs/Symptoms: RASH (12/6/04)

Is this correct? NO// y  YES
Enter Hospital Location:
Opening Adverse React/Allergy record for review...

Browse Document                Dec 06, 2004@14:02:53        Page:    1 of    1
                            Adverse React/Allergy
CPRSPATIENT,T  666-32-4321                        Visit Date: 12/06/2004 14:02

DATE OF NOTE: DEC 06, 2004@14:02:50  ENTRY DATE: DEC 06, 2004@14:02:52
      AUTHOR: CRPROVIDER,TWO              EXP COSIGNER:
     URGENCY:                             STATUS: UNSIGNED

This patient has had the following reactions
```

```
signed-off on Dec 06, 2004@14:02:50.

CHEESE




     + Next Screen  - Prev Screen  ?? More actions                >>>
     Find                       Sign/Cosign                Link ...
     Print                      Copy                       Encounter Edit
     Edit                       Identify Signers           Interdiscipl'ry Note
     Make Addendum              Delete                     Quit
Select Action: Quit//<Enter>
Select PATIENT NAME: <Enter>
```

FDA Enter/Edit Menu (Clinician)

This menu should be given to users responsible for the FDA portion of Adverse Reaction Tracking as designated by the site. The options on this menu allow users to enter and edit the FDA data.

1. Enter/Edit FDA Report Data
2. Enter/Edit P&T Committee Data

Enter/Edit FDA Report Data

This option allows users to enter and edit FDA-related data concerning an adverse reaction.

There are five sections to the FDA Report. Fields for Reaction Information (1) are shown in the example. Sections 2-5 are discussed below.

For Suspect Drug(s) Information (2) of the data entry, you may enter/edit the name of a suspect agent for the observed reaction, the daily dose given, route of administration, how the drug was given (SIG Code), the start and stop dates that it was administered, the name of the manufacturer, lot number, number of previous doses given, the last fill date, the drug's expiration date, the National Drug Code number and the indication/reason for the drug's use.

In the Concomitant Drugs and History section (3), you may enter/edit information about the drugs that the patient was taking at the time of the reaction. This includes the name of the drug, the start/stop dates of administration, the last fill date, and how the drug was given (SIG Code). You can also enter a word-processing type response to indicate any other related history for this drug.

In the Manufacturer Information section (4), you may enter/edit data concerning a manufacturer that should be notified, including the name of the manufacturer, address, the IND/NDA (Investigational New Drug/New Drug Application) number, the manufacturer's control number, the date the drug was received by the manufacturer, the source of the report (i.e., Health Professional), whether the 15-day report was completed and the type of the report (e.g., Initial).

The Initial Reporter (5) section allows you to enter/edit data concerning the person filling out the report, including name, address, phone number, whether the reporter is a health care provider, whether the name of the reporter should be disclosed to the manufacturer, and the reporter's occupational title.

```
Select FDA Enter/Edit Menu Option: 1 Enter/Edit FDA Report Data

Select PATIENT NAME: ARTpatient,Two 04-25-31 666001112 SC VETERAN

Select CAUSATIVE AGENT: ASPIRIN 10-04-69 666001112   SC VETERAN
        ASPIRIN
Select date reaction was OBSERVED (Time Optional): T-10 (JAN 13, 2004) JAN
  13, 1996 (JAN 13, 2004)
  Are you adding 'JAN 13, 2004as
  a new ADVERSE REACTION REPORTING? Y (Yes)
Indicate which FDA Report Sections to be completed:
1. Reaction Information
2. Suspect Drug(s) Information
3. Concomitant Drugs and History
4. Manufacturer Information
5. Initial Reporter
Choose number(s) of sections to be edited: (1-5): 1

The following is the list of reported signs/symptoms for this reaction:
    Signs/Symptoms
------------------------------------------------------------------------------
  1 ANXIETY

Select Action (A)DD OR (D)ELETE: A
```

```
The following are the top ten most common signs/symptoms:
1. ANXIETY 7. HIVES
2. ITCHING,WATERING EYES 8. DRY MOUTH
3. HYPOTENSION 9. CHILLS
4. DROWSINESS 10. RASH
5. CHEST PAIN 11. OTHER SIGN/SYMPTOM
6. DIARRHEA
Enter from the list above : 7

The following is the list of reported signs/symptoms for this reaction:

   Signs/Symptoms
------------------------------------------------------------------------------
  1 ANXIETY
  2 HIVES

Select Action (A)DD OR (D)ELETE: < Enter>

Patient died?: N NO
Reaction treated with RX drug?: N NO
Life Threatening illness?: N NO
Required hospitalization?: N NO
Prolonged Hospitalization?: N NO
Resulted in permanent disability?: N NO
Is this event a Congenital Anomaly?: N NO
Did this event require intervention to prevent impairment/damage?: N NO

THIS PATIENT HAS NO LAB TEST ON FILE FOR THIS ADVERSE REACTION REPORT
Select Action (A/D/E): ADD

View Tx/Test from: JAN 13, 2004// < Enter> (JAN 13, 2004)
To: JAN 13, 2004// < Enter> (JAN 13, 2004)

LAB TEST:
    Collection DT Test Name Specimen Results Hi/Low

    THERE IS NO LAB DATA FOR THIS PATIENT FOR THIS DATE RANGE.
Select TEST: ??

Choose from:
1,25-DIHYDROXYVIT D3
1/2HR LTT
1/2Hr.GTT
1/2Hr.GTT (URINE)
11-DEOXYCORTISOL
17-HYDROXYCORTICOSTEROIDS
17-HYDROXYPROGESTERONE
17-KETOGENIC STEROIDS
17-KETOSTEROIDS,TOTAL
1HR LTT
1Hr.GTT
1Hr.GTT (URINE)
25 OH VITAMIN D
2HR LTT
2Hr.GTT
2Hr.GTT (URINE)
3HR LTT
3Hr.GTT
3Hr.GTT (URINE)
4Hr.GTT
4Hr.GTT (URINE)
^
```

```
Select TEST: 1/2Hr.GTT (URINE)
Are you adding '1/2Hr.GTT (URINE)' as
a new RELEVANT TEST/LAB DATA (the 1ST for this ADVERSE REACTION
REPORTING)? Y (Yes)
RESULTS: ??
This field will contain the results for the particular test.
RESULTS: Enter results here.
COLLECTION D/T: T-10 (JAN 13, 2004)
Select TEST:
This patient has the following Test selected:
TEST/TX RESULTS DRAW DATE/TIME
1) 1/2Hr.GTT (URINE) Enter results here. 01/13/96
Select Action (A/D/E):

Indicate which FDA Report Sections to be completed: < Enter>
1. Reaction Information
2. Suspect Drug(s) Information
3. Concomitant Drugs and History
4. Manufacturer Information
5. Initial Reporter
Choose number(s) of sections to be edited: (1-5): < Enter>
```

Enter/Edit P&T Committee Data

This option will allow you to edit P&T data. It allows for the evaluation of a suspected Drug Reaction (ADR) by a qualified individual (e.g., clinical pharmacist, clinical pharmacologist), other than the attending physician.

You can also track a report to see if it has been sent to the FDA or manufacturer.

```
Select FDA Enter/Edit Menu Option: 2 Enter/Edit P&T Committee Data
Select PATIENT NAME: ARTpatient,One 10-04-69 666110111 SC VETERAN

Select CAUSATIVE AGENT: PENICILLIN 10-04-69 666110111  SC VETERAN PENICILLIN
Select date reaction was OBSERVED (Time Optional): T (JAN 24, 2004) JAN
24, 2004 (JAN 24, 2004)
  Are you adding 'JAN 24, 2004as
   a new ADVERSE REACTION REPORTING? Y (Yes)

P&T Report Completion
Serious ADR?: ??
   This field determines if the reaction is considered serious.
   Choose from:
     y YES
     n NO
Serious ADR?: y YES
ADR related to new drug?: n NO
Unexpected ADR?: y YES
ADR related to therapeutic failure?: n NO
Dose related?: n NO
P&T ACTION FDA REPORT: ??
     This field indicates if the P&T committee determined whether to send
     the report to FDA.
     Choose from:
       y YES
       n NO
P&T ACTION FDA REPORT: n NO
P&T ACTION MFR REPORT: n NO

ADDENDUM:
  1>ADD COMMENTS HERE
  2>
EDIT Option: < Enter>

Select PATIENT NAME: < Enter>
```

Reports Menu (Clinician)

This menu is part of the Adverse Reaction Tracking Clinician Menu. It is the only print option that the clinician needs for ART.

1. Active Listing of Patient Reactions
2. Print Patient Reaction Data
3. Print an FDA report for a Patient
4. List by Location of Unmarked ID Bands/Charts
5. Patient Allergies Not Signed Off
6. List by Location of Undocumented Allergies
7. List by Location Not Verified Reactions
8. List by Location and Date all Sign Reaction
9. List FDA data by Report Date

Active Listing of Patient Reactions

This option gives a brief listing of the active (data that is signed off and not entered in error) allergy/adverse reaction data for a particular patient. This report may be sent to a printer for a hard copy printout or displayed to the terminal screen. You may select a printer to get a hard copy printout, or display the report to the terminal screen.

The header of the display contains the report name, date and time it was run, patient's name, SSN, date of birth, and age. The body of the report divides the data by reaction type (e.g., Drug) and lists the causative agent, the signs/symptoms, and when they were observed or if they were historical, and whether it was verified. If the patient has no known reactions, the body of the report will display that the patient has no known allergies. If the patient was never asked if he/she has any allergy/adverse reactions, the body of the report will display a message stating that there are no reactions on file.

```
Select Reports Menu Option: 1 Active Listing of Patient Reactions

Select PATIENT: ARTpatient,One 10-04-69 666000111   ACTIVE DUTY

DEVICE: HOME// < Enter> HYPER SPACE



                  ACTIVE ALLERGY/ADVERSE REACTION LISTING
                      Run Date/Time: 7/6/04 1:51:13 pm
ARTPATIENT,ONE            666122222             APR 25,1931 (73)

                                                                        OBS/
 ADVERSE REACTION                                          VERIFIED     HIST
-------------------------------------------------------------------------------


   TYPE: DRUG
   ==========
ACETAMINOPHEN                                                NO         OBS
     Reactions: ANXIETY (Jun 06, 2001@10:21)
ACETANILIDE                                                  NO         HIST
     Reactions: CHILLS
ALOE VERA                                                    YES        OBS
     Reactions: ANXIETY (Mar 06, 1997)
ASPIRIN                                                      NO         HIST
     Reactions: RASH (Oct 31, 2001)
ASPIRIN/BUTALBITAL/CAFFEINE                                  NO         HIST
     Reactions: NAUSEA,VOMITING (Oct 31, 2001)
BARIUM SULFATE                                               YES        OBS
     Reactions: HIVES
BERROPLEX                                                    NO         HIST
     Reactions: DROWSINESS
CEPHALEXIN TABLETS, 250MG                                    YES        OBS
     Reactions: THROMBOCYTOPENIA
DILANTIN                                                     NO         OBS
     Reactions: CHILLS
ERYTHROMYCINS/MACROLIDES                                     YES        OBS
     Reactions: ITCHING,WATERING EYES (Mar 06, 1997)
GREEN SOAP                                                   YES        OBS
     Reactions: ANXIETY (May 19, 1997@14:25)
GREEN SOAP TINCTURE                                          YES        OBS
     Reactions: DRY MOUTH (May 19, 1997@14:23)
HALENOL 500MG CAPSULES                                       YES        HIST
     Reactions: ANXIETY (May 19, 1997@14:26)
HAYFEBROL SF                                                 NO         HIST
     Reactions: CHILLS, ITCHING,WATERING EYES
OPIOID ANALGESICS                                            NO         OBS
     Reactions: ITCHING,WATERING EYES
PENICILLIN                                                   NO         OBS
```

```
     Reactions: NAUSEA,VOMITING, DIARRHEA
PENICILLINS,AMINO DERIVATIVES                                YES       HIST
     Reactions: DEPRESSION (Jan 01, 1980)
RADIOLOGICAL/CONTRAST MEDIA                                  YES       OBS
     Reactions: HIVES
WARFARIN                                                     YES       OBS
     Reactions: HIVES (Mar 01, 1996)

   TYPE: DRUG, FOOD
   ================
ANTIRABIES SERUM                                             NO        OBS
     Reactions: CHILLS (Jun 08, 2004)
BEER                                                         NO        HIST
     Reactions: HYPOTENSION
SUNFLOWER OIL                                                NO        HIST

   TYPE: FOOD
   ==========
CHEESE                                                       YES       HIST
     Reactions: NAUSEA,VOMITING, DIARRHEA
FOLIC ACID                                                   YES       HIST
     Reactions: DRY NOSE
STRAWBERRIES                                                 YES       OBS
     Reactions: RASH
WATER                                                        NO        HIST
     Reactions: CHILLS
Enter  RETURN to continue or '^' to exit: ^
```

Print Patient Reaction Data

This option will allow you to get a captioned data display of all of the patient's allergy/adverse reaction data. You can send the report to a printer for a hard copy printout or have it displayed on the terminal screen.

You can select the types of reactions to include in the report. Any combination of types can be selected (i.e., FOOD and DRUG). You then select the status of the reaction entry. Any combination can be selected (i.e., ACTIVE and ENTERED IN ERROR).

The header of the report contains the title of the report, the date/time it was run, and the patient's name, SSN, date of birth, and age. The body contains the status of the reaction, its type, the name of the causative agent, any drug ingredients, any VA drug classes, the name of the person who entered the data, and the date and time it was entered. It also contains whether or not the data was signed off (completed), whether the reaction was observed or historical, whether the patient ID band or chart is marked, a list of the signs/symptoms, and additional comments made by the originator. A line of dots appears in the body of the report between the various reaction entries.

```
Select PATIENT: ARTPATIENT,TWO       4-25-31    666001112P     YES   MILITARY RETIREE
 Enrollment Priority: GROUP 2    Category: IN PROCESS    End Date:

Select 1:DRUG, 2:FOOD, 3:OTHER
Type of allergy:  (1-3): 1
Select 1:ACTIVE, 2:ENTERED IN ERROR
Which would you like to see?:  (1-2): 1

DEVICE: HOME// ;;999  ANYWHERE


                    ALLERGY/ADVERSE REACTION REPORTS
                    Run Date/Time: 7/6/04 1:54:59 pm
ARTPATIENT,TWO          666001112P            APR 25,1931 (73)
------------------------------------------------------------------------------

STATUS: ACTIVE
--------------
  TYPE: DRUG
  ==========

         AGENT: ACETAMINOPHEN
   INGREDIENTS: ALCOHOL                  VA DRUG CLASSES: NON-OPIOID ANALGESICS
                ACETAMINOPHEN                            PHARMACEUTICAL AIDS/R
                PHENYLALANINE

    ORIGINATOR: ARTPROVIDER,ONE              ORIGINATED: JUN 06, 2001@10:21
      SIGN OFF: YES                            OBS/HIST: OBSERVED

ID BAND MARKED:                             CHART MARKED:

SIGNS/SYMPTOMS: ANXIETY  (Jun 06, 2001@10:21)

     MECHANISM: UNKNOWN

.....................................................................
         AGENT: ACETANILIDE
   INGREDIENTS: ACETANILIDE              VA DRUG CLASSES: PHARMACEUTICAL AIDS/R

    ORIGINATOR: ARTPROVIDER,ONE                ORIGINATED: AUG 26, 2003@14:44
      SIGN OFF: YES                          OBS/HIST: HISTORICAL

ID BAND MARKED:                             CHART MARKED:

SIGNS/SYMPTOMS: CHILLS
```

```
     MECHANISM: UNKNOWN

.....................................................................
         AGENT: ALOE VERA
   INGREDIENTS: ALOE VERA                VA DRUG CLASSES: DERMATOLOGICALS,TOPIC

    ORIGINATOR: ARTPROVIDER,THREE               ORIGINATED: MAR 06, 1997@14:14
      SIGN OFF: YES                             OBS/HIST: OBSERVED

     ORIGINATOR
      COMMENTS:
          Date: Mar 06, 1997@14:14                 User: ARTNURSE,ONE
                                                  Title: NURSE
                TESTING


ID BAND MARKED:                              CHART MARKED:

SIGNS/SYMPTOMS: ANXIETY  (Mar 06, 1997)

     MECHANISM: UNKNOWN

      VERIFIER: AUTOVERIFIED                    VERIFIED: FEB 16, 2004@11:44:19

     VERIFIER
      COMMENTS:
          Date: Feb 16, 2004@11:44:19              User: ARTPROVIDER,ONE
                                                  Title: PHYSICIAN
                Auto-verified by patch 19 post-install


.Enter  RETURN to continue or '^' to exit: ^
```

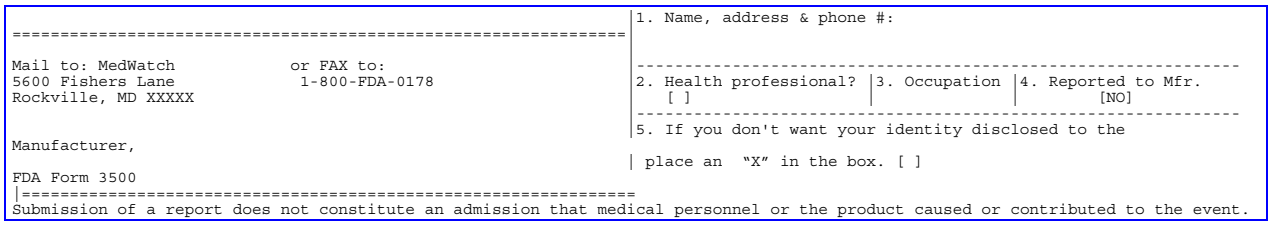
Print an FDA Report for a Patient

This option will allow you to print an individual FDA report for a patient.

This option will also produce a listing of all allergy/adverse reactions that are awaiting sign-off by the person entering the data into the system. The report should be queued to run on a printer with a 132-column width.

```
Select Reports Menu Option: 3 Print an FDA Report for a Patient
Select PATIENT NAME: ARTPATIENT,THREE 12-01-34 666124443 SC VETERAN
Select CAUSATIVE AGENT: ??

CHOOSE FROM:
   AMPICILLIN
   CYCLOSPORINE
   GENTAMICIN
   PENICILLIN

Select CAUSATIVE AGENT: AMPI 12-01-34 111124443 SC VETERAN
   AMPICILLIN
Select date reaction was OBSERVED (Time Optional): 1/10/96 (JAN 10,
1996).1249
      ...OK? Yes// (Yes)
THIS REPORT SHOULD BE SENT TO A 132 COLUMN PRINTER.

QUEUE TO PRINT ON
DEVICE: PRINTER 132 (132 COLUMN)

Requested Start Time: NOW// < Enter> (JAN 25, 1996@10:36:17)
Request queued...
```

```
MEDWatch                                                                    Approved by FDA on 10/20/93
------------------------------------------                                  ---------------------------------------------------
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM                                  | Triage unit sequence #
                                                                            |
------------------------------------------                                  --------------------------------------------------
                                                                            |
                                                    Page 1 of 1             --------------------------------------------------
============================================================================================================================
A. Patient Information                                   | C. Suspect Medication(s)
=========================================================|xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

1. Patient Indentifier|2. DOB: 12/1/34 |3. Sex|4. Weight |1. Name
T4443 | AGE: 61 yrs |FEMALE| 0.0                         | #1 : AMPICILLIN
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
                                                         |
B. Adverse Event or Product Problem                       |
-------------------------------------------------------- |-------------------------------------------------------------
1. [X]Adverse Event [ ]Product problem                   |2. Dose,frequency & route used | 3. Therapy dates
-------------------------------------------------------- | #1:                          |  #1 :
2. Outcomes attributed to adverse event                  |---------------               |--------------------------------
[ ] death:           [ ] disability                      |                              |
[ ] life-threatening [ ] congenital anomaly              |-------------------------------------------------------------
[ ] Hospitalization  [ ] required intervention to        |4.Diagnosis for use(indication)|5. Event abated after use
initial or prolonged prevent impairment/damage           |                              |  stopped or dose reduced?
                     [X] other                           | #1:                          |  #1: [N/A]
-------------------------------------------------------- |--------------------------------
3. Date of event                |4. Date of this report  |                              |
   01/10/96                     | 01/30/96               |-------------------------------------------------------------
-------------------------------------------------------- |6. Lot # (if known) |7. Exp. date|8. Event reappeared after
5. Describe event or problem                             |                    |            |  reintroduction
RASH                                                     | #1:                |  #1:       |  #1: [ ]
                                                         |--------------------|------------|---------------------------
                                                         |
                                                         |-------------------------------------------------------------
                                                         |9. (Not applicable to adverse drug event reports)
-------------------------------------------------------- |-------------------------------------------------------------
6. Relevant test/laboratory data. including dates        |10. Concomitant medical products/therapy dates(exclude
treatment)
                                                         |
                                                                |
                                                                |=============================================================
----------------------------------------------------------------|D. Suspect Medical Devices
7. Other relevant History, including preexisting medical        |-------------------------------------------------------------
conditions                                                      | Note: Please use the actual MedWatch form if the event
                                                                | involves a suspected device as well as a suspect drug
                                                                |=============================================================
                                                                |E. Reporter
                                                                |-------------------------------------------------------------
```


1. Name, address & phone #:
Mail to: MedWatch
5600 Fishers Lane
Rockville, MD XXXXX
or FAX to:
1-800-FDA-0178
2. Health professional?
[ ]
3. Occupation
4. Reported to Mfr.
[NO]
5. If you don't want your identity disclosed to the
Manufacturer,
place an "X" in the box. [ ]
FDA Form 3500
Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

List by Location of Unmarked ID Bands/Charts

This option will find all patients in the system who have not had their ID bands or charts marked. This option will also produce a list of all patients by ward/clinic who have not had their chart or ID bands marked. This report functions like the List of Patients Not Asked About Allergies option. It should be noted that you will be prompted to queue all reports except when choosing the Current Inpatients report by itself (i.e., #1).

```
Select Reports Menu Option: 4 List by Location of Unmarked ID Bands/Charts
       1 Current Inpatients
       2 Outpatients over Date/Time range
       3 New Admissions over Date/Time range
       4 All of the above
Enter the number(s) for those groups to be used in this report: (1-4): 4
Enter date/time range in which patients were
admitted into the hospital or seen at an outpatient clinic.

Enter START Date (time optional): T-90 (APR 07, 2004)
Enter END Date (time optional): T// < Enter> (JUL 06, 2004)
```

The location prompt allows you to select the ward or clinic that you want to print, or select all the wards/clinics by entering the word ALL, and the system will select all the appropriate hospital locations.

```
Select Location: ?

    You may deselect from the list by typing the - followed by location
    name.
    E.g. -3E would delete 3E from the list of locations already
    selected.
Answer with HOSPITAL LOCATION NAME, or ABBREVIATION
Choose from:
   1A
   1S
   GMC DR. PETIT
   PHYSICAL EXAM
Select Location: 1A
Another Location: < Enter>

QUEUE TO PRINT ON
DEVICE: SELECT APPROPRIATE PRINTER
Requested Start Time: NOW// < Enter> (JUL 6 2004@13:42:26)
Request queued...

Jul 6,2004            PATIENTS WITH UNMARKED ID BAND/CHART            PAGE 1
               CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
                      FROM Apr 7,2004      TO Jul 6,2004@24:00

PATIENT                         SSN            ALLERGY              UNMARKED
--------------------------------------------------------------------------------

          WARD: 1A(1&2)
ARTPATIENT,ONE              666-00-0111      Da DRUG              ID BAND/CHART
                                             DUST                 ID BAND/CHART
                                             AMPICILLIN           ID BAND/CHART
                                             ASPIRIN              ID BAND/CHART
                                             CHOCOLATE            ID BAND/CHART
                                             MILK OF MAGNESIA     ID BAND/CHART
                                             AMOXICILLIN          ID BAND/CHART
                                             PENICILLIN           ID BAND/CHART
                                             MENTHOL              ID BAND/CHART
ARTPATIENT,TWO                666-00-1112    AMOXICILLIN          ID BAND/CHART
                                             DUST                 ID BAND/CHART
```

		ZANTAC	ID BAND/CHART
ARTPATIENT,THREE	666-00-1113	CEPHALEXIN TABLETS,	ID BAND/CHART
		CHEESE	ID BAND/CHART
		BARIUM SULFATE	ID BAND/CHART
		OPIOID ANALGESICS	ID BAND/CHART
		RADIOLOGICAL/CONTRAS	ID BAND/CHART
		FOLIC ACID	ID BAND/CHART
		STRAWBERRIES	ID BAND/CHART
ARTPATIENT,FOUR	666-00-1114	STRAWBERRIES	ID BAND/CHART
ARTPATIENT,FIVE	666-00-1115	CHOCOLATE	ID BAND/CHART
		BLUE CROSS AMPICILLI	ID BAND/CHART
		ACETAMINOPHEN TAB	ID BAND/CHART
		STRAWBERRIES	ID BAND/CHART
		ASPIRIN/BUTALBITAL	ID BAND/CHART

Patient Allergies Not Signed Off

This option prints allergy/adverse reactions for patients that have not been signed off (completed) by the user entering data. Users who have the GMRA-ALLERGY VERIFY key will see all reactions that are not signed off. Users who do not have that key will see just the entries that they created. You may select a printer to get a hard copy printout or display the report to the terminal screen.

The header of the report contains the name of the report and the date and time that it was run. The body of the report lists the name of the person who entered the date, the patient's name followed by the last four digits of the SSN, the causative agent, and the date/time the entry was made.

```
Select Reports Menu Option: 5 Patient Allergies Not Signed Off
DEVICE: HOME// < Enter> HYPER SPACE
ALLERGY/ADVERSE REACTIONS TO BE SIGNED OFF
Run Date/Time: 1/18/96 1:23:52 pm
ORIGINATOR       PATIENT                   ALLERGY      ORIGINATION DATE/TIME
------------------------------------------------------------------------
ARTPROVIDER,ONE   ARTPATIENT,ONE (0111)    PENICILLIN        FEB 18, 1993@10:59
ARTPROVIDER,ONE   ARTPATIENT,ONE (0111)    FROG              FEB 18, 1993@15:14
ARTPROVIDER,ONE   ARTPATIENT,TWO (0112)    THORAZINE 10MG    FEB 22, 1993@13:20
ARTPROVIDER,ONE   ARTPATIENT,THREE (0113)  PENICILLIN        JUN 22, 1993@11:44
ARTPROVIDER,ONE   ARTPATIENT,THREE (0113)  PHENYTOIN         JUN 22, 1993@11:48
ARTPROVIDER,ONE   ARTPATIENT,THREE (0113)  DEMECARIUM        JUN 22, 1993@12:00
ARTPROVIDER,ONE   ARTPATIENT,THREE (0113)  ASPIRIN           JUN 22, 1993@12:08
ARTPROVIDER,ONE   ARTPATIENT,FOUR (0114)   PHENOBARBITAL     JUN 25, 1993@10:33
ARTPROVIDER,ONE   ARTPATIENT,THREE (0113)  PHENOBARBITAL     JUN 25, 1993@10:39
ARTPROVIDER,ONE   ARTPATIENT,TWO (0112)    CODEINE           JUN 30, 1993@08:55
ARTPROVIDER,ONE   ARTPATIENT,FIVE (0115)   THOR - PROM       AUG 11, 1993@10:35
ARTPROVIDER,ONE   ARTPATIENT,FIVE (0115)   IMMUNE GLOBULIN   AUG 18, 1993@10:02
ARTPROVIDER,ONE   ARTPATIENT,FIVE (0115)   CYCLOBENZAPRINE   JUL 11, 1994@14:11
ARTPROVIDER,ONE   ARTPATIENT,FIVE (0115)   SULFABENZAMIDE/S  JUL 11, 1994@14:14
Enter  RETURN to continue or '^' to exit: ^
```

List by Location of Undocumented Allergies

This report is used to list all patients in the patient database who have never been asked if they have any known allergies. It should be noted that you will be prompted to queue all reports except stand-alone Current Inpatients' reports. The header of the report contains the date the report was run, title of the report, the list of the groups included (i.e., current inpatients), and any date ranges entered. The body of the report categorizes the patients by clinic or ward. It lists the patient's name, SSN, and provider. The room-bed will appear for current inpatients.

```
Select Adverse Reaction Tracking User Menu Option: 6 List by Location of Undocumented
Allergies
    1 Current Inpatients
    2 Outpatients over Date/Time range
    3 New Admissions over Date/Time range
    4 All of the above
Enter the number(s) for those groups to be used in this report: (1-4): 4
 Enter date/time range in which patients were
 admitted into the hospital or seen at an outpatient clinic.

Enter START Date (time optional): T-180  (JAN 08, 2004)
Enter END Date (time optional): T//   (JUL 06, 2004)
Select Location:    2B MED
Another Location: 1A(1&2)
Another Location:<Enter>
QUEUE TO PRINT ON
DEVICE: SELECT APPROPRIATE PRINTER
Requested Start Time: NOW// < Enter> (JAN 19, 1996@10:29:44)
Request queued...

Jul 6,2004              PATIENTS NOT ASKED ABOUT ALLERGIES             PAGE 1
               CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
                       FROM Jan 8,2004    TO Jul 6,2004@24:00

PATIENT                         SSN            PROVIDER
------------------------------------------------------------------------------

          WARD: 1A(1&2)
ARTPATIENT,FIVE               666-00-0115    ARTPROVIDER,ONE
ARTPATIENT,THREE              666-00-0113
ARTPATIENT,TWO                666-00-0112    ARTPROVIDER,TWO
     Room/Bed: B-2
ARTPATIENT,FOUR               666-00-0114    ARTPROVIDER,FOUR
     Room/Bed: 9-B
Enter RETURN to continue or '^' to exit:<Enter>

Jul 6,2004              PATIENTS NOT ASKED ABOUT ALLERGIES             PAGE 2
               CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
                       FROM Jan 8,2004    TO Jul 6,2004@24:00

PATIENT                         SSN            PROVIDER
------------------------------------------------------------------------------

          WARD: 2B MED
ARTPATIENT,SIX                666-00-0116    ARTPROVIDER,FOUR
ARTPATIENT,SEVEN              666-00-0117    ARTPROVIDER,FOUR
Enter RETURN to continue or '^' to exit: <Enter>
```

List by Location Not Verified Reactions

This option prints a list of patient reactions that have not been verified. The data is sorted by hospital location, patient, and reaction. You can send the report to a printer for a hard copy or to the terminal screen. This report can be scheduled to automatically run at a regular interval (e.g., daily). Contact your ADPAC or IRM support person to schedule this report to automatically run. The option name to schedule this report to automatically run is GMRA TASK A/AR NV.

The header of this report contains the name of the report, the date it was run, and the hospital location. The body contains the patient's name and SSN, the causative agent, the name of the originator of the reaction, and the date/time of data origination. The Room-Bed is also displayed for each patient.

```
Select Reports Menu Option: 7  List by Location Not Verified Reactions


DEVICE: HOME//   ANYWHERE

Report Date: Jul 06, 2004                                      Page: 1
                  List of Unverified Reactions by Ward Location
                              Ward Location: 13A PSYCH
   Origination Date/Time      Originator              Reaction
------------------------------------------------------------------------------
ARTPATIENT,ONE (666-00-0111)
   Jul 16, 2003@11:49         ARTPROVIDER,ONE         RANITIDINE
ARTPATIENT,TWO (666-00-0112)
   Jul 09, 1996@08:04         ARTPROVIDER,TWO         STRAWBERRIES
ARTPATIENT,THREE (666-00-0113)
   Jul 09, 1996@08:04         ARTPROVIDER,TWO         DUST
ARTPATIENT,FOUR (666-00-0114)
   Jul 09, 1996@08:04         ARTPROVIDER,TWO         FISH LIVER OIL
ARTPATIENT,FIVE (666-00-0115)
   May 24, 1999@14:21         ARTPROVIDER,THREE       MILK
   Jul 02, 1999@13:40         ARTPROVIDER,THREE       BERGAMOT
   Aug 20, 1999@09:27         ARTPROVIDER,THREE       RANITIDINE
Enter RETURN to continue or '^' to exit:
```

List by Location and Date all Signed Reactions

This option prints a list of all patient reactions that have been signed off (completed) for a user supplied date range. The data is sorted by location and date range. This report can be sent to a printer for a hard copy printout or displayed on your terminal screen.
The header of the report contains the title, the date range selected by you, the date that the report was run, and the hospital location. The body of the report contains the patient's name and SSN, the causative agent's name and type, the name of the data's originator, and the date/time of data origination.

```
Select Reports Menu Option:  List by Location and Date All Signed
Reactions
Enter Start Date: t-180  (JAN 08, 2004)
Enter Ending Date: t  (JUL 06, 2004)


DEVICE: HOME//   ANYWHERE

One moment please...

Jul 06, 2004                                                  Page: 1
           List all Signed Patient Reactions for Ward Location 1A(1&2)
               From Jan 08, 2004 to Jul 06, 2004@24:00
Date                 Originator               Type Causative Agent
------------------------------------------------------------------------
          Patient: ARTPATIENT,SIX (666-00-0116)
Jan 12, 2004@12:56  ARTPROVIDER,ONE               D   HAYFEBROL SF
Jun 11, 2004@15:25  ARTPROVIDER,TWO               D   DIRITHROMYCIN
Jun 08, 2004@12:15  ARTPROVIDER,THREE             DF  ANTIRABIES SERUM

          Patient: ARTPATIENT,SEVEN (666-00-0117)
Feb 26, 2004@11:29  ARTPROVIDER,ONE             D   ZANTAC
May 04, 2004@10:52  ARTPROVIDER,ONE             D   FORMALDEHYDE
May 04, 2004@10:55  ARTPROVIDER,ONE             D   CONTACT LENS WETTING
SOLN
May 04, 2004@10:56  ARTPROVIDER,ONE             D   NICO 400
May 04, 2004@10:57  ARTPROVIDER,ONE             DF  CORN
May 04, 2004@11:00  ARTPROVIDER,ONE             DF  BCG VACCINE

          Patient: ARTPATIENT,EIGHT (666-00-0118)
Feb 26, 2004@11:31  ARTPROVIDER,ONE             D   ZANTAC

          Patient: ARTPATIENT,NINE (666-00-0119)
Feb 05, 2004@10:51  ARTPROVIDER,TWO             F   STRAWBERRIES
Enter RETURN to continue or '^' to exit:
```

List FDA Data by Report Date

This option displays a report of FDA data that tracks when a reaction was observed and when it was entered into the database. You must enter a date range. This report can be printed or sent to the terminal screen.

The header of the report contains the name of the report, the date range that you selected, and the date that the report was run. The body of the report contains the patient's name and SSN, the name of the causative agent, the patient's location, the observation date of the reaction, the date the reaction was actually reported, the difference (i.e., the number of days) between the observation date and when it was reported, and the name of the person who observed the reaction.

```
Select Reports Menu Option: 9  List FDA Data by Report Date
Select a Tracking date range for this report.
Enter Start Date: t-180  (JAN 08, 2004)
Enter Ending Date: t  (JUL 06, 2004)


DEVICE: HOME//   ANYWHERE

Report Date: Jul 06, 2004                                      Page: 1
                      Adverse Reaction Tracking Report
                         From: 1/8/04 To: 7/6/04
Patient                                  Dates    Related Reaction
-------------------------------------------------------------------------
ARTPATIENT,ONE                  Obs DT: 1/27/04  DUST
(666-00-1111)                   Trk DT: 1/27/04
Loc: 1A(1&2)                    -------------
Obs: ARTPROVIDER,ONE              0 Days Difference

ARTPATIENT,TWO                  Obs DT: 1/30/04  CHOCOLATE
(666-00-1112)                   Trk DT: 1/30/04
Loc: OUT PATIENT                -------------
Obs: ARTPROVIDER,ONE            0 Days Difference

ARTPATIENT,THREE                Obs DT: 1/30/04  CHOCOLATE
(355-67-1996)                   Trk DT: 1/30/04
Loc: 8E REHAB MED               -------------
Obs: ARTPROVIDER,ONE            0 Days Difference

ARTPATIENT,FOUR                 Obs DT: 2/2/04   ZANTAC
(666-00-0114)                   Trk DT: 2/2/04
Loc: 1A(1&2)                    -------------
Obs: ARTPROVIDER,ONE             0 Days Difference

Enter RETURN to continue or '^' to exit:
```

Edit Chart and ID Band

This option allows you to enter whether a patient's ID band or the chart has been marked. It should be used by the personnel charged with the responsibility of making sure that the patient's paper chart has been marked to indicate that an allergy/adverse reaction is present. You select a patient and the various causative agents associated with that patient are displayed. Any number of agents may be selected by you to indicate whether the patient chart has been marked.

```
Select Adverse Reaction Tracking Clinician Menu Option: 4 Edit Chart and
ID Band

Select Patient: ARTPATIENT,ONE 10-04-69 666122222 SC VETERAN

CHOOSE FROM:
   ASPIRIN
   COD LIVER OIL
   DEMECARIUM
   FROGS
   PENBUTOLOL
   PENICILLIN
   PHENOBARBITAL
   PHENYTOIN
   PREDNISONE
   THOR - PROM
   TIMOLOL
   TYLOXAPOL

Select CAUSATIVE AGENT: ASPIRIN 10-04-69 123122222 SC VETERAN
ASPIRIN

Select another CAUSATIVE AGENT: PENICILLIN 10-04-69 123122222
SC VETERAN PENICILLIN
Select another CAUSATIVE AGENT: < Enter>
This session you have CHOSEN:
    PENICILLIN
    ASPIRIN

Has the ID Band been marked for these CAUSATIVE AGENTS? ??
    ANSWER YES IF THE ID Band HAS BEEN MARKED, ELSE ANSWER NO
Have the Chart(s) been marked for these CAUSATIVE AGENTS? Y (Yes)
```

Adverse Reaction Tracking Verifier Menu

This menu should be given to the verifiers of the Adverse Reaction Tracking data. The options on this menu will allow you to edit/verify/print the data.

This menu should *only* be given to the verifiers of ART.

1. Enter/Edit Patient Reaction Data
2. Verify Patient Reaction Data
3. Reports Menu ...
4. Edit Chart and ID Band
5. FDA Enter/Edit Menu ...
6 Online Reference Card

Enter/Edit Patient Reaction Data

This option allows users to enter and edit patient allergies/adverse reactions. You are prompted to enter the name of the agent that caused the reaction, whether the reaction was observed during the patient's stay/visit at the facility, any signs or symptoms associated with the reaction, the date and time the sign/symptom occurred, the type of reaction (i.e., mechanism), any appropriate comments concerning the entry, and whether the patient's chart is marked for this reaction.

See Page 10 for descriptions of the prompts for this option.

Example

```
Select Adverse Reaction Tracking Verifier Menu Option: 1  Enter/Edit Patient Reaction
Data

Select PATIENT NAME: ARTPATIENT,ONE        1-1-51    666111995     NO     EMPLOYEE
 Enrollment Priority: GROUP 7    Category: IN PROCESS    End Date:

                                                                      OBS/
REACTANT                                              VER.   MECH.   HIST  TYPE
--------                                              ----  -------  ----  ----
CHOCOLATE                                             AUTO  ALLERGY  HIST  DRUG
 (CHOCOLATE FLAVORING)                                                     FOOD
    Reactions: CHILLS, DROWSINESS, DRY MOUTH

Enter Causative Agent: straw

Checking existing PATIENT ALLERGIES (#120.8) file for matches...


Now checking GMR ALLERGIES (#120.82) file for matches...
BERRIES
   STRAWBERRIES   OK? Yes// <Enter>   (Yes)


(O)bserved or (H)istorical Allergy/Adverse Reaction: o  OBSERVED
Select date reaction was OBSERVED (Time Optional):  t  (DEC 06, 2004)   DEC 06,
2004  (DEC 06, 2004)
  Are you adding 'DEC 06, 2004' as
    a new ADVERSE REACTION REPORTING? No// y  (Yes)


No signs/symptoms have been specified.  Please add some now.

The following are the top ten most common signs/symptoms:
 1. CHILLS                          7. HIVES
 2. ITCHING,WATERING EYES           8. DRY MOUTH
 3. HYPOTENSION                     9. DRY NOSE
 4. DROWSINESS                     10. RASH
 5. NAUSEA,VOMITING                11. OTHER SIGN/SYMPTOM
 6. DIARRHEA
Enter from the list above :  10
Date(Time Optional) of appearance of Sign/Symptom(s): Dec 06, 2004//<Enter>  (DEC 06,
2004)


The following is the list of reported signs/symptoms for this reaction:

     Signs/Symptoms                                   Date Observed
```

```
---------------------------------------------------------------------------
  1  RASH                                              Dec 06, 2004

Select Action (A)DD, (D)ELETE OR <RET>: <Enter>


COMMENTS:
  1>
Complete the observed reaction report? Yes// <Enter>  (Yes)
DATE/TIME OF EVENT: DEC 6,2004// <Enter>
OBSERVER:  ARTPROVIDER,TEN     TA          PHYSICIAN
SEVERITY: mi  MILD
DATE MD NOTIFIED: Dec 6,2004// <Enter>  (DEC 06, 2004)
Enter another Causative Agent? YES// n  NO

                              Dec 06, 2004@15:01:50
Causative Agent Data edited this Session:
ADVERSE REACTION
----------------
  STRAWBERRIES

          Obs/Hist: OBSERVED
           Obs d/t: Dec 06, 2004
    Signs/Symptoms: RASH (12/6/04)

Is this correct? NO// y  YES

Opening Adverse React/Allergy record for review...


Browse Document               Dec 06, 2004@15:01:50          Page:    1 of    1
                            Adverse React/Allergy
CPRSPATIENTCANC666-11-1995   2B MED            Adm: 02/18/2003  Dis:

DATE OF NOTE: DEC 06, 2004@15:01:49  ENTRY DATE: DEC 06, 2004@15:01:50
      AUTHOR: ARTPROVIDER,TEN            EXP COSIGNER:
     URGENCY:                            STATUS: UNSIGNED

This patient has had the following reactions
signed-off on Dec 06, 2004@15:01:49.

STRAWBERRIES


          + Next Screen  - Prev Screen  ?? More actions                  >>>
     Find                     Sign/Cosign              Link ...
     Print                    Copy                     Encounter Edit
     Edit                     Identify Signers         Interdiscipl'ry Note
     Make Addendum            Delete                   Quit
Select Action: Quit// s
Enter your Current Signature Code: xxxxxx SIGNATURE VERIFIED
Print this note? Yes// n (No)
Enter another Causative Agent? YES// n NO
This session you have CHOSEN:
     STRAWBERRIES

Has the ID Band been marked for this CAUSATIVE AGENT? y  (Yes)??

Select PATIENT NAME: < Enter>
```

Verify Patient Reaction Data

This option allows designated verifiers to verify the correctness of data entered by the clinical users. The verifier may select a single patient's data to verify or a list or range (e.g., 1,3,7 or 1-10) of patients to verify. The verifier may select to view/verify drug reactions only, non-drug reactions only, or drug and non-drug reactions. The reaction data is displayed and the verifier may edit the causative agent, type, ingredients, drug class, observed/historical response, signs/symptoms, and mechanism. The verifier may enter any appropriate comments.

If the verifier answers YES to the "change status of this allergy/adverse reaction to verified" prompt, the reaction will be marked as verified. If the verifier answers NO to that prompt, the reaction is marked as entered in error.

If no hospital location is associated with the patient, the verifier will be prompted to enter a location.

A progress note is created. The verifier may electronically sign, edit, or delete the progress note. The verifier may print the progress note, too.

```
Select Adverse Reaction Tracking Verifier Menu Option: 2  Verify Patient
Reaction Data
Would you like to verify a single patient's data? NO// YES

Select PATIENT NAME: CPRSPATIENT,FIVE        4-30-44    666466680     YES
 EMPLOYEE
 Enrollment Priority: GROUP 2    Category: IN PROCESS    End Date:


                   D  Drug
                   N  Non-drug
                   B  Both
Select type of AGENT to verify:(D/N/B): DRUG


                                                          OBS/
  PATIENT                              ALLERGY            HIST ADR TYPE
  -------                              -------            ---- --- ----
1. CPRSPATIENT,FIVE (6680) 1A(1&2)   ANTIRABIES SERUM     OBS  UNK DRUG
                                                                  FOOD
2. CPRSPATIENT,FIVE (6680) 1A(1&2)   ASPARTAME           OBS  UNK DRUG
                                                                  FOOD
3. CPRSPATIENT,FIVE (6680) 1A(1&2)   ASPIRIN             HIST UNK DRUG
                                                                  FOOD
Select a number between 1-3: 1

       PATIENT: CPRSPATIENT,FIVE         CAUSATIVE AGENT: ANTIRABIES SERUM
   INGREDIENTS: ANTIRABIES SERUM         VA DRUG CLASSES: IMMUNE SERUMS

    ORIGINATOR: ARTPROVIDER,ONE           ORIGINATED: Jun 08, 2004@12:15
      SIGN OFF: YES                             OBS/HIST: OBSERVED
                                                 OBS D/T: Jun 08, 2004@12:15

     ORIGINATOR
      COMMENTS:
          Date: Jun 08, 2004@12:16:50              User: CPRSPROVIDER,TWO
                                                  Title:
                chills and sweating
```

```
ID BAND MARKED:                                  CHART MARKED:

SIGNS/SYMPTOMS: CHILLS  (Jun 08, 2004@12:15)

     MECHANISM: UNKNOWN
Is the reaction information correct? Yes// <Enter>  (Yes)


CAUSATIVE AGENT: ANTIRABIES SERUM
           TYPE: DRUG, FOOD
    INGREDIENTS: ANTIRABIES SERUM
VA DRUG CLASSES: IM400 - IMMUNE SERUMS
       OBS/HIST: OBSERVED

 SIGNS/SYMPTOMS: CHILLS  (Jun 08, 2004@12:15)
      MECHANISM: UNKNOWN

Would you like to edit any of this data? N  (No)

     ORIGINATOR
      COMMENTS:
          Date: Jun 08, 2004@12:16:50              User: CPRSPROVIDER,TWO
                                                  Title:
                chills and sweating

COMMENTS:
  1>
       PATIENT: CPRSPATIENT,FIVE         CAUSATIVE AGENT: ANTIRABIES SERUM
   INGREDIENTS: ANTIRABIES SERUM         VA DRUG CLASSES: IMMUNE SERUMS

    ORIGINATOR: ARTPROVIDER,TWO                ORIGINATED: Jun 08, 2004@12:15
      SIGN OFF: YES                             OBS/HIST: OBSERVED
                                                 OBS D/T: Jun 08, 2004@12:15


     ORIGINATOR
      COMMENTS:
          Date: Jun 08, 2004@12:16:50              User: CPRSPROVIDER,TWO
                                                  Title:
                chills and sweating


Enter RETURN to continue or '^' to exit:



                              Dec 06, 2004@15:51:38
ID BAND MARKED:                                  CHART MARKED:

SIGNS/SYMPTOMS: CHILLS  (Jun 08, 2004@12:15)

     MECHANISM: UNKNOWN
```

```
Change status of this allergy/adverse reaction to verified? Y  (Yes)

Opening Adverse React/Allergy record for review...


Browse Document                Dec 06, 2004@15:51:38        Page:    1 of    1
                             Adverse React/Allergy
CPRSPATIENT,FIVE  666-46-6680   1A(1&2)           Adm: 10/15/2001  Dis:

DATE OF NOTE: DEC 06, 2004@15:51:37  ENTRY DATE: DEC 06, 2004@15:51:37
      AUTHOR: ARTPROVIDER,ONE          EXP COSIGNER:
     URGENCY:                            STATUS: UNSIGNED
```

```
This patient has had an allergy to ANTIRABIES SERUM
verified on Dec 06, 2004@15:51:37.


       + Next Screen  - Prev Screen  ?? More actions                    >>>
     Find                      Sign/Cosign               Link ...
     Print                     Copy                      Encounter Edit
     Edit                      Identify Signers          Interdiscipl'ry Note
     Make Addendum             Delete                    Quit
Select Action: Quit//
```

NOTE: Users can enter/edit their own electronic signature code.

Reports Menu (Verifier)

This menu is part of the Adverse Reaction Tracking Verifier Menu. It is the only print menu that the verifier will need for ART.

1. Active Listing of Patient Reactions
2. Print Patient Reaction Data
3. Print an FDA report for a Patient
4. Print all FDA events within D/T range
5. Print Patient FDA Exception Data
6. Print all FDA Exceptions within a D/T range
7. List by Location of Unmarked ID Bands/Charts
8. Patient Allergies Not Signed Off
9. List by Location of Undocumented Allergies
10. List Autoverified Reaction Data
11. List by Location Not Verified Reactions
12. List by Location and Date all Sign Reactions
13. List FDA Data by Report Date

Active Listing of Patient Reactions

This option gives a brief listing of the active (data that is signed off and not entered in error) allergy/adverse reaction data for a particular patient. You may select a printer to get a hard copy printout, or display the report to the terminal screen.

The header of the display contains the report name, date and time it was run, patient's name, SSN, date of birth, and age. The body of the report divides the data by reaction type (e.g., Drug) and lists the causative agent, the signs/symptoms, and when they were observed or if they were historical, and whether it was verified.

If the patient has no known reactions, the body of the report will display that the patient has no known allergies. If the patient was never asked if he/she has any allergy/adverse reactions, the body of the report will display a message stating that there are no reactions on file.

```
Select PATIENT:    ARTPATIENT,TWO 2-22-42    666000112    YES     ACTIVE DUTY
 Enrollment Priority:           Category: IN PROCESS    End Date:

DEVICE: HOME// ;;999  ANYWHERE


                  ACTIVE ALLERGY/ADVERSE REACTION LISTING
                    Run Date/Time: 6/25/04 11:56:58 am
ARTPATIENT,TWO          666-00-0112             FEB 22,1942 (62)

                                                                      OBS/
 ADVERSE REACTION                                          VERIFIED   HIST
-------------------------------------------------------------------------------


   TYPE: DRUG
   ==========
ALLENT                                                       YES       HIST
ALUMINUM ACETATE                                             YES       HIST
     Reactions: CHILLS (Nov 25, 2002)
AMOXICILLIN                                                  NO        HIST
AMPICILLIN                                                   NO        HIST
BILBERRY                                                     YES       HIST
CANDESARTAN                                                  YES       HIST
CARAMEL                                                      YES       HIST
     Reactions: HIVES (Jan 22, 1998),
                ITCHING,WATERING EYES (Jan 22, 1998)
CORICIDIN TAB                                                YES       OBS
     Reactions: CHILLS, HYPOTENSION, NAUSEA,VOMITING
CORN STARCH                                                  YES       HIST
CORRECTOL                                                    YES       HIST
CORTICOTROPIN                                                YES       HIST
CORTICOTROPIN/ZINC HYDROXIDE                                 YES       HIST
EYE WASHES/LUBRICANTS                                        NO        OBS
     Reactions: DROWSINESS
FILGRASTIM                                                   YES       HIST
HAYFEBROL SF                                                 NO        HIST
     Reactions: ITCHING,WATERING EYES
LOMEFLOXACIN                                                 YES       OBS
     Reactions: ITCHING,WATERING EYES (Mar 10, 1999)
OXYCODONE                                                    YES       HIST
PENICILLINS                                                  NO        HIST
PENTAMIDINE                                                  YES       HIST
PENTAZOCINE                                                  YES       HIST
PENTETIC ACID                                                YES       HIST
```

```
RANITIDINE                                                      YES       OBS
     Reactions: CHILLS (Nov 26, 2002@11:16)
TACRINE                                                         YES       HIST
TAPE                                                            YES       HIST
TAVIST                                                          NO        HIST
TAVIST                                                          NO        HIST
WARFARIN                                                        YES       HIST
WATER                                                           NO        HIST
ZANTAC                                                          YES       HIST

   TYPE: DRUG, FOOD
   ================
CHOCOLATE                                                       YES       HIST
FLUPHENAZINE DECANOATE                                          NO        HIST
PEANUT OIL                                                      NO        OBS
     Reactions:
                ITCHING,WATERING EYES (Oct 05, 2000@24:00),
                ANXIETY (Oct 06, 2000@09:27)
SHELL FISH                                                      NO        HIST

   TYPE: FOOD
   ==========
NUTS                                                            YES       HIST
     Reactions: HIVES (Jan 02, 1998)
PEACHES                                                         YES       HIST
STRAWBERRIES                                                    YES       HIST

   TYPE: OTHER
   ===========
DUST                                                            YES       HIST
Enter RETURN to continue or '^' to exit:
```

Print Patient Reaction Data

This option allows you to get a captioned data display of all of the patient's allergy/adverse reaction data. You can send the report to a printer for a hard copy printout or have it displayed on the terminal screen.

You can select the types of reactions to include in the report. Any combination of types can be selected (i.e., FOOD and DRUG). You then select the status of the reaction entry. Any combination can be selected (i.e., ACTIVE and ENTERED IN ERROR).

The header of the report contains the title of the report, the date/time it was run, and the patient's name, SSN, date of birth, and age. The body contains the status of the reaction, its type, the name of the causative agent, any drug ingredients, any VA drug classes, the name of the person who entered the data, and the date and time it was entered. It also contains whether or not the data was signed off (completed), whether the reaction was observed or historical, whether the patient ID band or chart is marked, a list of the signs/symptoms, and additional comments made by the originator. A line of dots appears in the body of the report between the various reaction entries.

```
Select Adverse Reaction Tracking User Menu Option: 7 Print Patient Reaction
Data

Select PATIENT: ARTPATIENT,ONE 10-12-69 666000111 SC VETERAN
Select 1:DRUG, 2:FOOD, 3:OTHER
Type of allergy: (1-3): 1
Select 1:ACTIVE, 2:ENTERED IN ERROR
Which would you like to see?: (1-2): 1

DEVICE: HOME// < Enter> HYPER SPACE

                    ALLERGY/ADVERSE REACTION REPORTS
                     Run Date/Time: 7/2/04 9:18:55 am
ARTPATIENT,ONE          666-00-0111             FEB 22,1942 (62)
------------------------------------------------------------------------------

STATUS: ACTIVE
--------------
  TYPE: DRUG
  ==========

         AGENT: ALLENT
   INGREDIENTS: PSEUDOEPHEDRINE          VA DRUG CLASSES: ANTIHISTAMINE/DECONGE
                BROMPHENIRAMINE

    ORIGINATOR: ARTPROVIDER,TWO                 ORIGINATED: MAR 17, 2004@14:34
      SIGN OFF: YES                             OBS/HIST: HISTORICAL

ID BAND MARKED:                                CHART MARKED: MAR 17, 2004@14:34:16


     MECHANISM: ALLERGY

Enter RETURN to continue or '^' to exit:


                     ALLERGY/ADVERSE REACTION REPORTS
                     Run Date/Time: 7/2/04 9:18:55 am
ARTPATIENT,ONE          666-00-0111             FEB 22,1942 (62)
------------------------------------------------------------------------------
```

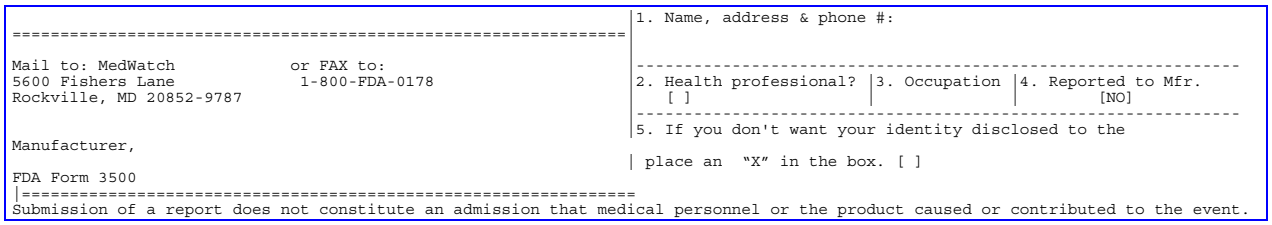
```
      VERIFIER: AUTOVERIFIED                    VERIFIED: MAR 17, 2004@14:34:17

.....................................................................
         AGENT: ALUMINUM ACETATE
   INGREDIENTS: ALUMINUM ACETATE         VA DRUG CLASSES:

    ORIGINATOR: ARTPROVIDER,ONE                 ORIGINATED: NOV 26, 2002@11:25
      SIGN OFF: YES                             OBS/HIST: HISTORICAL

ID BAND MARKED:                              CHART MARKED:

SIGNS/SYMPTOMS: CHILLS  (Nov 25, 2002)

     MECHANISM: UNKNOWN

      VERIFIER: AUTOVERIFIED                    VERIFIED: NOV 26, 2002@11:26:27
Enter RETURN to continue or '^' to exit:


                    ALLERGY/ADVERSE REACTION REPORTS
                    Run Date/Time: 7/2/04 9:18:55 am
ARTPATIENT,ONE          666-00-0111             FEB 22,1942 (62)
---------------------------------------------------------------------------


.....................................................................
         AGENT: AMOXICILLIN
   INGREDIENTS: AMOXICILLIN              VA DRUG CLASSES: PENICILLINS,AMINO DER

    ORIGINATOR: ARTPROVIDER,TWO                 ORIGINATED: JAN 21, 1998@10:20
      SIGN OFF: YES                             OBS/HIST: HISTORICAL

ID BAND MARKED:                              CHART MARKED:


     MECHANISM: UNKNOWN

.....................................................................
         AGENT: AMPICILLIN
   INGREDIENTS: AMPICILLIN               VA DRUG CLASSES:

Enter RETURN to continue or '^' to exit:


                    ALLERGY/ADVERSE REACTION REPORTS
                    Run Date/Time: 7/2/04 9:18:55 am
ARTPATIENT,ONE          666-00-0111             FEB 22,1942 (62)
---------------------------------------------------------------------------

    ORIGINATOR: ARTPROVIDER,ONE                 ORIGINATED: JAN 21, 1998@10:25
      SIGN OFF: YES                             OBS/HIST: HISTORICAL

ID BAND MARKED:                              CHART MARKED:


     MECHANISM: UNKNOWN
```

Print an FDA Report for a Patient

This option allows you to print an individual FDA report for a patient. This option will produce a listing of all allergy/adverse reactions that are awaiting sign off by the person entering the data into the system. The report should be queued to run on a printer with a 132-column width.

```
Select Reports Menu Option: 3 Print an FDA Report for a Patient
Select PATIENT NAME: ARTPATIENT,TWO 12-01-34 6660001112 SC VETERAN
Select CAUSATIVE AGENT: ??

CHOOSE FROM:
   AMPICILLIN
   CYCLOSPORINE
   GENTAMICIN
   PENICILLIN

Select CAUSATIVE AGENT: AMPI 12-01-34 111124443 SC VETERAN
   AMPICILLIN
Select date reaction was OBSERVED (Time Optional): 1/10/96 (JAN 10,
1996).1249
     ...OK? Yes// (Yes)
THIS REPORT SHOULD BE SENT TO A 132 COLUMN PRINTER.

QUEUE TO PRINT ON
DEVICE: PRINTER 132 (132 COLUMN)

Requested Start Time: NOW// < Enter> (JAN 25, 1996@10:36:17)
Request queued...
```

```
MEDWatch                                                                  Approved by FDA on 10/20/93
-----------------------------------------                                  ---------------------------------------------------
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM                                |  Triage unit sequence #
                                                                          |
-----------------------------------------                                 ---------------------------------------------------
                                                                          |
                                                                          |
                                                    Page 1 of 1           ---------------------------------------------------
========================================================================================================================
A. Patient Information                                   | C. Suspect Medication(s)
=========================================================|xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

1. Patient Indentifier|2. DOB: 12/1/34 |3. Sex|4. Weight |1. Name
T0112 | AGE: 61 yrs |FEMALE| 0.0                         | #1 : AMPICILLIN
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
                                                         |
B. Adverse Event or Product Problem                      |
---------------------------------------------------------|----------------------------------------------------------------
1. [X]Adverse Event [ ]Product problem                   |2. Dose,frequency & route used | 3. Therapy dates
---------------------------------------------------------| #1:                          | #1 :
2. Outcomes attributed to adverse event                  |----------------                |---------------------------------
[ ] death:            [ ] disability                     |                               |
[ ] life-threatening [ ] congenital anomaly              |----------------------------------------------------------------
[ ] Hospitalization  [ ] required intervention to        |4.Diagnosis for use(indication)|5. Event abated after use
initial or prolonged prevent impairment/damage           |                               | stopped or dose reduced?
                     [X] other                           | #1:                           | #1: [N/A]
---------------------------------------------------------|---------------------------------
3. Date of event                  |4. Date of this report |                               |
   01/10/96                       | 01/30/96              |----------------------------------------------------------------
---------------------------------------------------------|6. Lot # (if known) |7. Exp. date|8. Event reappeared after
5. Describe event or problem                             |                    |            | reintroduction
RASH                                                     | #1:                | #1:        | #1: [ ]
                                                         |--------------------|------------|---------------------------
                                                         |                    |            |
                                                         |----------------------------------------------------------------
                                                         |9. (Not applicable to adverse drug event reports)
---------------------------------------------------------|----------------------------------------------------------------
6. Relevant test/laboratory data. including dates        |10. Concomitant medical products/therapy dates(exclude
treatment)                                               |
                                                         |
                                                                |
                                                                |
                                                                |================================================================
----------------------------------------------------------------|D. Suspect Medical Devices
7. Other relevant History, including preexisting medical        |----------------------------------------------------------------
conditions                                                      | Note: Please use the actual MedWatch form if the event
                                                                | involves a suspected device as well as a suspect drug
                                                                |================================================================
                                                                |E. Reporter
                                                                |----------------------------------------------------------------
```


1. Name, address & phone #:
Mail to: MedWatch
5600 Fishers Lane
Rockville, MD 20852-9787
or FAX to:
1-800-FDA-0178
2. Health professional?
[ ]
3. Occupation
4. Reported to Mfr.
[NO]
5. If you don't want your identity disclosed to the
Manufacturer,
place an "X" in the box. [ ]
FDA Form 3500
Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Print all FDA Events Within D/T Range

This report prints all the FDA reports over a given date range, entered by you. You may choose to print Complete FDA Adverse Event Reports or an abbreviated listing of reports. Complete reports should be queued to a printer that has 132-column width. An abbreviated listing may be sent to a printer or CRT. If an abbreviated listing is chosen and if the report has been sent to the FDA, the listing will display the date that the report was sent.

```
Select Reports Menu Option: 4  Print All FDA Events within D/T Range
Select Start Date/Time:  T-30  (JUN 07, 2004)
Select End Date/Time:  (6/7/2004 - 7/7/2004): T// <Enter>  (JUL 07, 2004)
Do you want an Abbreviated report? Yes// <Enter>    (Yes)


DEVICE: HOME//<Enter>    ANYWHERE

Jul 07, 2004@07:38:46                                          Page: 1
                              FDA ABBREVIATED REPORT
PATIENT                         SUSPECTED AGENT               D/T OF EVENT
------------------------------------------------------------------------------

ARTPATIENT,ONE  (666-00-0111)    ANTIRABIES SERUM             Jun 8,2004
ARTPATIENT,TWO  (666-00-0112)    ANTIRABIES SERUM             Jun 8,2004@12:15
ARTPATIENT,THREE(666-00-0113)    SHRIMP                       Jun 15,2004
ARTPATIENT,FOUR (666-00-0114)    ZANAMIVIR                    Jun 21,2004
ARTPATIENT,FOUR (666-00-0114)    ACYCLOVIR                    Jun 21,2004
ARTPATIENT,FOUR (666-00-0114)    RANITIDINE                   Jun 21,2004
ARTPATIENT,FOUR (666-00-0114)    ZANAMIVIR                    Jun 21,2004@08:27
ARTPATIENT,FIVE (666-00-0115)    SHRIMP                       Jun 28,2004
ARTPATIENT,FIVE (666-00-0115)    FLOXURIDINE                  Jun 30,2004
ARTPATIENT,FIVE (666-00-0115)    FORMOTEROL                   Jun 30,2004
ARTPATIENT,FIVE (666-00-0115)    FORMALDEHYDE                 Jun 30,2004
Enter RETURN to continue or '^' to exit: <Enter>
```

Print Patient FDA Exception Data

This option allows you to print a list of all observed or drug allergies from a given date to the present for a patient that has been signed off (completed), but is missing sign/symptom data. You select a patient and the date from which to start the search.
The header of the report contains the name of the report and the date/time that it was run. The body contains the patient's name, SSN, the causative agent, the origination date/time of the entry and name of the originator.

```
Select Reports Menu Option: 5 Print Patient FDA Exception Data

Select PATIENT NAME: ARTPATIENT,ONE  ARTPATIENT,ONE        2-22-42    666000111
YES     ACTIVE DUTY
 Enrollment Priority:            Category: NOT ENROLLED  End Date: 07/06/2004

Enter the Date to start search (Time optional):  T-30// t-60  (MAY 08, 2004)


DEVICE: HOME// <Enter>    ANYWHERE

Jul 7,2004 07:42:26                                              Page: 1
                    FDA EXCEPTION REPORT (Starting at 5/8/04)
ORIGINATION D/T     CAUSATIVE AGENT               ORIGINATOR
-------------------------------------------------------------------------------

     Patient: ARTPATIENT,ONE (666-00-0111)
Jun 30,2004@10:31   FLOXURIDINE                   ARTPROVIDER,ONE
Jun 30,2004@10:34   FORMOTEROL                    ARTPROVIDER,ONE
Jun 30,2004@10:39   FORMALDEHYDE                  ARTPROVIDER,ONE
Enter RETURN to continue or '^' to exit: <Enter>
```

Print all FDA Exceptions within a D/T Range

This option allows you to select a date range from which to print a list of all patients who had an Observed Drug Reaction that has not been reported to the FDA. The report can be sent to a printer or to your terminal screen. The header of the report contains the name of the report, the date range selected by you and the date/time that the report was run. The body of the report contains the patient's name and SSN, the causative agent, the name of the person who originated the data entry, and the origination date/time of the data.

```
Select Reports Menu Option: 6  Print All FDA Exceptions within a D/T Range
Select Start Date:  T-90  (APR 08, 2004)
Select End Date:  (4/8/2004 - 7/7/2004): T// <Enter>  (JUL 07, 2004)


DEVICE: HOME// <Enter>    ANYWHERE

Jul 7,2004 07:37:28                                              Page: 1
                   FDA EXCEPTION REPORT (4/8/04 to 7/7/04)
ORIGINATION D/T     CAUSATIVE AGENT               ORIGINATOR
-------------------------------------------------------------------------------

     Patient: ARTPATIENT,ONE (666-00-0111)
Jun 8,2004@12:21    ANTIRABIES SERUM              ARTPROVIDER,ONE
     Patient: ARTPATIENT,TEN (666-00-0110)
Jun 8,2004@12:15    ANTIRABIES SERUM              ARTPROVIDER,ONE
     Patient: ARTPATIENT,TWO (666-00-0112)
Jun 30,2004@10:31   FLOXURIDINE                   ARTPROVIDER,ONE
Jun 30,2004@10:34   FORMOTEROL                    ARTPROVIDER,TWO
Jun 30,2004@10:39   FORMALDEHYDE                  ARTPROVIDER,THREE
     Patient: ARTPATIENT,THREE (666-00-0113)
Jun 16,2004@08:27   SHRIMP                        ARTPROVIDER,ONE
     Patient: ARTPATIENT,FOUR (666-00-0114)
Apr 30,2004@09:33   PENICILLIN                    ARTPROVIDER,ONE
     Patient: ARTPATIENT,FIVE (666-00-0115)
May 20,2004@12:09   LEAD ACETATE PURIFIED POWDER  ARTPROVIDER,FOUR
Jun 21,2004@08:23   ZANAMIVIR                     ARTPROVIDER,ONE
Jun 21,2004@08:38   ACYCLOVIR                     ARTPROVIDER,FOUR
Jun 21,2004@09:43   RANITIDINE                    ARTPROVIDER,TWO
Enter RETURN to continue or '^' to exit: <Enter>
```

List by Location of Unmarked ID Bands/Charts

This option will produce a list of all patients by ward/clinic who have not had their chart or ID bands marked. This report functions like the List of Patients Not Asked About Allergies option. It should be noted that you will be prompted to queue all reports except when choosing the Current Inpatients report by itself (i.e., #1).

The header of the report contains the date the report was run, title of the report, the list of the groups included (i.e., inpatients), and any date ranges entered by you. The body of the report categorizes the patients by clinic or ward. It lists the patient's name, SSN, name of the causative agent, and whether the patient ID band, patient chart, or both were unmarked.

```
Select Reports Menu Option: 7  List by Location of Unmarked ID Bands/Charts
     1 Current Inpatients
     2 Outpatients over Date/Time range
     3 New Admissions over Date/Time range
     4 All of the above
Enter the number(s) for those groups to be used in this report: (1-4):4
 Enter date/time range in which patients were
 admitted into the hospital or seen at an outpatient clinic.

Enter START Date (time optional): t-90  (APR 08, 2004)
Enter END Date (time optional): T// <Enter>  (JUL 07, 2004)
```

The location prompt allows you to select the ward or clinic that you want to print, or select all the wards/clinics by entering the word ALL and the system will select all the appropriate hospital locations.

```
Jun 28,2004           PATIENTS WITH UNMARKED ID BAND/CHART           PAGE 1
               CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
                      FROM Mar 30,2004     TO Jun 28,2004@24:00

PATIENT                       SSN            ALLERGY              UNMARKED
--------------------------------------------------------------------------------

          WARD: 1A(1&2)
ARTPATIENT,ONE               666-00-0111    DAVE DRUG            ID BAND/CHART
                                            DUST                 ID BAND/CHART
                                            AMPICILLIN           ID BAND/CHART
                                            ASPIRIN              ID BAND/CHART
                                            CHOCOLATE            ID BAND/CHART
                                            MILK OF MAGNESIA     ID BAND/CHART
                                            AMOXICILLIN          ID BAND/CHART
                                            PENICILLIN           ID BAND/CHART
                                            MENTHOL              ID BAND/CHART
ARTPATIENT,TWO                666-00-0112    AMOXICILLIN          ID BAND/CHART
                                            DUST                 ID BAND/CHART
                                            ZANTAC               ID BAND/CHART
ARTPATIENT,THREE              666-00-0113    CEPHALEXIN TABLETS,  ID BAND/CHART
Enter RETURN to continue or '^' to exit:

Jun 28,2004           PATIENTS WITH UNMARKED ID BAND/CHART           PAGE 2
               CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
                      FROM Mar 30,2004     TO Jun 28,2004@24:00

PATIENT                       SSN            ALLERGY              UNMARKED
--------------------------------------------------------------------------------
                                            CHEESE               ID BAND/CHART
                                            BARIUM SULFATE       ID BAND/CHART
```

```
                                          OPIOID ANALGESICS    ID BAND/CHART
                                          RADIOLOGICAL/CONTRAS ID BAND/CHART
                                          FOLIC ACID           ID BAND/CHART
                                          STRAWBERRIES         ID BAND/CHART
                                          PENICILLIN           ID BAND/CHART
Jun 28,2004           PATIENTS WITH UNMARKED ID BAND/CHART           PAGE 3
               CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
                      FROM Mar 30,2004     TO Jun 28,2004@24:00

PATIENT                        SSN            ALLERGY              UNMARKED
--------------------------------------------------------------------------------
                                          ACETANILIDE          ID BAND/CHART
                                          ANTIRABIES SERUM     ID BAND/CHART
ARTPATIENT,FOUR                666-00-0114    STRAWBERRIES         ID BAND/CHART
ARTPATIENT,FIVE                666-00-0115    CHOCOLATE            ID BAND/CHART
                                          BLUE CROSS AMPICILLI ID BAND/CHART
                                          ACETAMINOPHEN TAB    ID BAND/CHART
                                          STRAWBERRIES         ID BAND/CHART
Enter RETURN to continue or '^' to exit:
```

Patient Allergies Not Signed Off

This option prints allergy/adverse reactions for patients that have not been signed off (completed) by users entering data. Users who have the GMRA-ALLERGY VERIFY key will see all reactions that are not signed off. Users who do not have that key will see just the entries that they created. You may select a printer to get a hard copy printout or display the report to the terminal screen.

The header of the report contains the name of the report and the date and time that it was run. The body of the report lists the name of the person who entered the date, the patient's name followed by the last four digits of the SSN, the causative agent, and the date/time the entry was made.

```
Select Adverse Reaction Tracking User Menu Option: 5 Patient Allergies
Not Signed Off
Include deceased patients on report? NO// <Enter>

DEVICE: HOME// < Enter> HYPER SPACE
                 ALLERGY/ADVERSE REACTIONS TO BE SIGNED OFF
                      Run Date/Time: 6/28/04 9:18:26 am

ORIGINATOR              PATIENT            ALLERGY        ORIGINATION
DATE/TIME
--------------------------------------------------------------------------
PROVIDER,ONE ARTPATIENT,ONE  (0111) PENICILLIN FEB 18, 2003@10:59
PROVIDER,ONE ARTPATIENT,ONE  (0111) FROG FEB 18, 2003@15:14
PROVIDER,ONE ARTPATIENT,ONE  (0111) THORAZINE 10MG FEB 22, 2003@13:20
PROVIDER,ONE ARTPATIENT,TWO  (0112) PENICILLIN JUN 22, 2003@11:44
PROVIDER,ONE ARTPATIENT,TWO  (0112) PHENYTOIN JUN 22, 2003@11:48
PROVIDER,ONE ARTPATIENT,TWO  (0112) DEMECARIUM JUN 22, 2003@12:00
PROVIDER,ONE ARTPATIENT,TWO  (0112) ASPIRIN JUN 22, 2003@12:08
PROVIDER,ONE ARTPATIENT,TWO  (0112) PHENOBARBITAL JUN 25, 2003@10:33
PROVIDER,ONE ARTPATIENT,TWO  (0112) PHENOBARBITAL JUN 25, 2003@10:39
PROVIDER,ONE ARTPATIENT,TWO  (0112) CODEINE JUN 30, 2003@08:55
PROVIDER,ONE ARTPATIENT,TWO  (0112) THOR - PROM AUG 11, 2003@10:35
PROVIDER,ONE ARTPATIENT,TWO  (0112) IMMUNE GLOBULIN AUG 18, 2003@10:02
PROVIDER,ONE ARTPATIENT,THREE (0113)  CYCLOBENZAPRINE JUL 11, 2004@14:11
PROVIDER,ONE ARTPATIENT,THREE (0113)  SULFABENZAMIDE/S JUL 11, 2004@14:14
PROVIDER,ONE ARTPATIENT,THREE (0114)  DUCK JAN 06, 2004@11:13
Enter  RETURN to continue or '^' to exit: ^
```

List by Location of Undocumented Allergies

This report is used to list all patients in the patient database who have never been asked if they have any known allergies. It should be noted that you will be prompted to queue all reports except stand-alone Current Inpatients' reports. The header of the report contains the date the report was run, title of the report, the list of the groups included (i.e., current inpatients), and any date ranges entered. The body of the report categorizes the patients by clinic or ward. It lists the patient's name, SSN, and provider. The room-bed will appear for current inpatients.

```
Select Adverse Reaction Tracking User Menu Option: 6 List by Location of
Undocumented Allergies
       1 Current Inpatients
       2 Outpatients over Date/Time range
       3 New Admissions over Date/Time range
       4 All of the above
Enter the number(s) for those groups to be used in this report:(1-4): 4
 Enter date/time range in which patients were
 admitted into the hospital or seen at an outpatient clinic.

Enter START Date (time optional): T-180 (JAN 04, 2004)
Enter END Date (time optional): T// <Enter> (JUL 02, 2004)
```

The location prompt allows you to select the ward or clinic that you want to print, or select all the wards/clinics by entering the word ALL, and the system will select all the appropriate hospital locations.

```
Select Location: ??

    You may deselect from the list by typing a '-' followed by location name.
    E.g. -3E would delete 3E from the list of locations already selected.
    You may enter the word ALL to select all appropriate locations.
 Answer with HOSPITAL LOCATION NAME, or ABBREVIATION
Choose from:
  Choose from:
   1 DR'S CLINIC
   13A PSYCH
   1A(1&2)
   2B MED
   8E REHAB MED
   8W SUBSTANCE ABUSE
   CARDIOLOGY
   CT ROOM

Select Location: 1A
Another Location: 2B
Another Location: Cardiology
Another Location: < Enter>

QUEUE TO PRINT ON
DEVICE: SELECT APPROPRIATE PRINTER

Requested Start Time: NOW// < Enter> (JUL 2, 2004@10:24:00)
Request queued...
```

```
Jul 2,2004             PATIENTS NOT ASKED ABOUT ALLERGIES            PAGE 1
               CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
                       FROM Jan 4,2004    TO Jul 2,2004@24:00

PATIENT                        SSN            PROVIDER
------------------------------------------------------------------------------

         WARD: 1A(1&2)
ARTPATIENT,ONE             666-00-0111    ARTPROVIDER,ONE
ARTPATIENT,TWO             666-00-1112P
ARTPATIENT,TWO             666-00-1112
                                          ARTPROVIDER,TWO
     Room/Bed: B-2
ARTPATIENT,THREE           666-12-4443    ARTPROVIDER,THREE
     Room/Bed: 9-B
ARTPATIENT,FOUR            666-00-1114
ARTPATIENT,FIVE            666-00-1115
Enter RETURN to continue or '^' to exit:

Jul 2,2004             PATIENTS NOT ASKED ABOUT ALLERGIES            PAGE 2
               CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
                       FROM Jan 4,2004    TO Jul 2,2004@24:00

PATIENT                        SSN            PROVIDER
------------------------------------------------------------------------------

         WARD: 2B MED
ARTPATIENT,SIX             666-00-1116    ARTPROVIDER,FOUR
ARTPATIENT,SEVEN           666-00-1117
Enter RETURN to continue or '^' to exit:


Jul 2,2004             PATIENTS NOT ASKED ABOUT ALLERGIES            PAGE 3
               CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
                       FROM Jan 4,2004    TO Jul 2,2004@24:00

PATIENT                        SSN
------------------------------------------------------------------------------

         CLINIC: CARDIOLOGY
ARTPATIENT,EIGHT           666-00-1118        ARTPROVIDER,FIVE
ARTPATIENT,NINE            666-00-1119
ARTPATIENT,TEN             666-00-1110
Enter RETURN to continue or '^' to exit:
```

List Autoverified Reaction Data

This option lists autoverified reaction data by date/time range, location, and mechanism. It also displays previous sorting values that were used during this session. The first time that you run the report during this session, those previous values will be "not null." If you run the option again, the previous sorting values will display (e.g., *Previous Selection: Verification Date/Time from 1/1/96 to 1/31/96@24:00).

The header of this report contains the name of the report, the date it was run, and the date range entered. The body of the report contains the data sorted, first by ward location, then by mechanism, and finally by verification date. The report contains the patient's name, the last digits in the SSN, room-bed, the causative agent, the signs/symptoms, the name of the person who originated the entry and any comments entered by the originator.

```
Select Reports Menu Option: 10  List Autoverified Reaction Data
* Previous selection: VERIFICATION DATE/TIME from Feb 1,1996 to Feb
29,1996@24:00
START WITH VERIFICATION DATE/TIME: Feb 1,1996// <Enter>   (FEB 01, 1996)
GO TO VERIFICATION DATE/TIME: Feb 29,1996// T  (JUL 07, 2004)
      * Previous selection: PATIENT:WARD LOCATION equals 1S
      START WITH WARD LOCATION: 1S// 1A
      GO TO WARD LOCATION: 1S// 2B
          * Previous selection: MECHANISM equals A (ALLERGY)
          START WITH NATURE OF REACTION: A// <Enter>     ALLERGY
          GO TO NATURE OF REACTION: A// <Enter>     ALLERGY
DEVICE: <Enter>     ANYWHERE    Right Margin: 80// <Enter>
07/07/04   LIST OF AUTOVERIFIED ALLERGIES FROM 02/01/96 TO 07/07/04    Page: 1

PATIENT                   ROOM-BED    REACTANT                     VER. DATE
------------------------------------------------------------------------------


WARD LOCATION: 1A(1&2)

    MECHANISM: ALLERGY

ARTPATIENT,ONE (0001)               BEEF                          JAN  7,1999
  ORIGIN.:  ARTPROVIDER,ONE
    SIGNS:  NAUSEA,VOMITING
            DIFFICULTY SWALLOWING
 COMMENTS:  Testing ART/TIU interface.

ARTPATIENT,TWO (0002)              STRAWBERRIES                MAY  7,2004
  ORIGIN.:  ARTPROVIDER,TWO
    SIGNS:  HIVES
 COMMENTS:
```

List by Location Not Verified Reactions

This option prints a list of patient reactions that have not been verified. The data is sorted by hospital location, patient, and reaction. You can send the report to a printer for a hard copy or to the terminal screen. This report can be scheduled to automatically run at a regular interval (e.g., daily). Contact your ADPAC or IRM support person to schedule this report to automatically run. The option name to schedule this report to automatically run is GMRA TASK A/AR NV.
The header of this report contains the name of the report, the date it was run, and the hospital location. The body contains the patient's name and SSN, the causative agent, the name of the originator of the reaction, and the date/time of data origination. The Room-Bed is also displayed for each patient.

```
Select Reports Menu Option: 11  List by Location Not Verified Reactions


DEVICE: HOME// <Enter>  ANYWHERE

Report Date: Jul 07, 2004                                        Page: 1
                    List of Unverified Reactions by Ward Location
                               Ward Location: 13A PSYCH
   Origination Date/Time      Originator               Reaction
-------------------------------------------------------------------------
ARTPATIENT,ONE (666-00-0111)
   Jul 16, 2003@11:49         ARTPROVIDER,ONE          RANITIDINE
ARTPATIENT,TWO (666-00-0112)
   Jul 09, 1996@08:04         ARTPROVIDER,TWO          STRAWBERRIES
ARTPATIENT,THREE (666-00-0113)
   Jul 09, 1996@08:04         ARTPROVIDER,TWO          DUST
ARTPATIENT,FOUR (666-00-0114)
   Jul 09, 1996@08:04         ARTPROVIDER,TWO          FISH LIVER OIL
ARTPATIENT,FIVE (666-00-0115)
   May 24, 1999@14:21         ARTPROVIDER,THREE        MILK
   Jul 02, 1999@13:40         ARTPROVIDER,THREE        BERGAMOT
   Aug 20, 1999@09:27         ARTPROVIDER,THREE        RANITIDINE
Enter RETURN to continue or '^' to exit:
```

List by Location and Date all Signed Reactions

This option prints a list of all patient reactions that have been signed off (completed) for a user-supplied date range. The data is sorted by location and date range. This report can be sent to a printer for a hard copy printout or displayed on your terminal screen.

The header of the report contains the title, the date range selected, the date that the report was run, and the hospital location. The body of the report contains the patient's name and SSN, the causative agent's name and type, the name of the data's originator, and the date/time of data origination.

```
Select Reports Menu Option:  List by Location and Date All Signed
Reactions
Enter Start Date: t-180  (JAN 08, 2004)
Enter Ending Date: t  (JUL 06, 2004)


DEVICE: HOME//<Enter>   ANYWHERE

One moment please...

Jul 06, 2004                                                  Page: 1
           List all Signed Patient Reactions for Ward Location 1A(1&2)
               From Jan 08, 2004 to Jul 06, 2004@24:00
Date                 Originator               Type Causative Agent
------------------------------------------------------------------------
          Patient: ARTPATIENT,SIX (666-00-0116)
Jan 12, 2004@12:56  ARTPROVIDER,ONE               D   HAYFEBROL SF
Jun 11, 2004@15:25  ARTPROVIDER,TWO               D   DIRITHROMYCIN
Jun 08, 2004@12:15  ARTPROVIDER,THREE             DF  ANTIRABIES SERUM

          Patient: ARTPATIENT,SEVEN (666-00-0117)
Feb 26, 2004@11:29  ARTPROVIDER,ONE             D   ZANTAC
May 04, 2004@10:52  ARTPROVIDER,ONE             D   FORMALDEHYDE
May 04, 2004@10:55  ARTPROVIDER,ONE             D   CONTACT LENS WETTING
SOLN
May 04, 2004@10:56  ARTPROVIDER,ONE             D   NICO 400
May 04, 2004@10:57  ARTPROVIDER,ONE             DF  CORN
May 04, 2004@11:00  ARTPROVIDER,ONE             DF  BCG VACCINE

          Patient: ARTPATIENT,EIGHT (666-00-0118)
Feb 26, 2004@11:31  ARTPROVIDER,ONE             D   ZANTAC

          Patient: ARTPATIENT,NINE (666-00-0119)
Feb 05, 2004@10:51  ARTPROVIDER,TWO             F   STRAWBERRIES
Enter RETURN to continue or '^' to exit:
```

List FDA Data by Report Date

This option displays a report of FDA data that tracks when a reaction was observed and when it was entered into the database. You must enter a date range. This report can be printed or sent to the terminal screen.

The header of the report contains the name of the report, the date range that you selected, and the date that the report was run. The body of the report contains the patient's name and SSN, the name of the causative agent, the patient's location, the observation date of the reaction, the date the reaction was actually reported, the difference (i.e., the number of days) between the observation date and when it was reported, and the name of the person who observed the reaction.

```
Select Reports Menu Option: 9  List FDA Data by Report Date
Select a Tracking date range for this report.
Enter Start Date: t-180  (JAN 08, 2004)
Enter Ending Date: t  (JUL 06, 2004)


DEVICE: HOME//   ANYWHERE

Report Date: Jul 06, 2004                                      Page: 1
                      Adverse Reaction Tracking Report
                         From: 1/8/04 To: 7/6/04
Patient                                  Dates    Related Reaction
-------------------------------------------------------------------------
ARTPATIENT,ONE                  Obs DT: 1/27/04  DUST
(666-00-1111)                   Trk DT: 1/27/04
Loc: 1A(1&2)                    -------------
Obs: ARTPROVIDER,ONE              0 Days Difference

ARTPATIENT,TWO                  Obs DT: 1/30/04  CHOCOLATE
(666-00-1112)                   Trk DT: 1/30/04
Loc: OUT PATIENT                -------------
Obs: ARTPROVIDER,ONE            0 Days Difference

ARTPATIENT,THREE                Obs DT: 1/30/04  CHOCOLATE
(355-67-1996)                   Trk DT: 1/30/04
Loc: 8E REHAB MED               -------------
Obs: ARTPROVIDER,ONE            0 Days Difference

ARTPATIENT,FOUR                 Obs DT: 2/2/04   ZANTAC
(666-00-0114)                   Trk DT: 2/2/04
Loc: 1A(1&2)                    -------------
Obs: ARTPROVIDER,ONE             0 Days Difference

Enter RETURN to continue or '^' to exit:
```

Edit Chart and ID Band

This option allows you to designate that a patient's ID band or the chart has been marked. It should be used by the personnel charged with the responsibility of making sure that the patient's paper chart has been marked to indicate that an allergy/adverse reaction is present. You select a patient and the various causative agents associated with that patient are displayed. Any number of agents may be selected by you to indicate whether the patient chart has been marked.

```
Select Adverse Reaction Tracking Verifier Menu Option: 4 Edit Chart and ID Band

Select Patient: ARTPATIENT,TWO 10-04-69 6660000112 SC VETERAN

CHOOSE FROM:
   ASPIRIN
   COD LIVER OIL
   DEMECARIUM
   FROGS
   PENBUTOLOL
   PENICILLIN
   PHENOBARBITAL
   PHENYTOIN
   PREDNISONE
   THOR - PROM
   TIMOLOL
   TYLOXAPOL

Select CAUSATIVE AGENT: ASPIRIN 10-04-69 6660000112 SC VETERAN
ASPIRIN

Select another CAUSATIVE AGENT: PENICILLIN 10-04-69 6660000112
SC VETERAN PENICILLIN
Select another CAUSATIVE AGENT: < Enter>
This session you have CHOSEN:
    PENICILLIN
    ASPIRIN
Has the ID Band been marked for this CAUSATIVE AGENT? Y  (Yes)
```

FDA Enter/Edit Menu (Verifier)

This menu should be given to people responsible for the FDA portion of Adverse Reaction Tracking as designated by the site. The options on this menu will allow you to edit the FDA data.

1. Enter/Edit FDA Report Data
2. Enter/Edit P&T Committee Data

Enter/Edit FDA Report Data

This option allows users to enter and edit FDA-related data concerning an adverse reaction.

There are five sections to the FDA Report. Fields for Reaction Information (1) are shown in the example. Sections 2-5 are discussed below.

For Suspect Drug(s) Information (2) of the data entry, you may enter/edit the name of a suspect agent for the observed reaction, the daily dose given, route of administration, how the drug was given (SIG Code), the start and stop dates that it was administered, the name of the manufacturer, lot number, number of previous doses given, the last fill date, the drug's expiration date, the National Drug Code number and the indication/reason for the drug's use.

In the Concomitant Drugs and History section (3), you may enter/edit information about the drugs that the patient was taking at the time of the reaction. This includes the name of the drug, the start/stop dates of administration, the last fill date, and how the drug was given (SIG Code). You can also enter a word-processing-type response to indicate any other related history for this drug.

In the Manufacturer Information section (4), you may enter/edit data concerning a manufacturer that should be notified, including the name of the manufacturer, address, the IND/NDA (Investigational New Drug/New Drug Application) number, the manufacturer's control number, the date the drug was received by the manufacturer, the source of the report (e.g., Health Professional), whether the 15-day report was completed, and the type of the report (i.e., Initial).

The Initial Reporter (5) section allows you to enter/edit data concerning the person filling out the report, including name, address, phone number, whether the reporter is a health care provider, whether the name of the reporter should be disclosed to the manufacturer, and the reporter's occupational title.

```
Select FDA Enter/Edit Menu Option: 1  Enter/Edit FDA Report Data

Select PATIENT NAME: ARTPATIENT,ONE     2-22-42    666000111     YES     ACTIVE DUTY
 Enrollment Priority:            Category: NOT ENROLLED  End Date: 07/06/2004

Select CAUSATIVE AGENT: FLOXURIDINE, PATIENT  ARTPATIENT,ONE   2-22-42    666000111
     YES     ACTIVE DUTY
 Enrollment Priority:            Category: NOT ENROLLED  End Date: 07/06/2004
       FLOXURIDINE
Select date reaction was OBSERVED (Time Optional):  6/30/04  (JUN 30, 2004)
         ...OK? Yes// <Enter>  (Yes)

Indicate which FDA Report Sections to be completed:
1.  Reaction Information
2.  Suspect Drug(s) Information
3.  Concomitant Drugs and History
4.  Manufacturer Information
5.  Initial Reporter
Choose number(s) of sections to be edited:  (1-5): 1

The following is the list of reported signs/symptoms for this reaction:
          These reactions were entered by another user:
     Signs/Symptoms
-------------------------------------------------------------------------------
     RASH
```

```
Select Action (A)DD OR <RET>: A

The following are the top ten most common signs/symptoms:
 1. CHILLS                          7. HIVES
 2. ITCHING,WATERING EYES           8. DRY MOUTH
 3. HYPOTENSION                     9. DRY NOSE
 4. DROWSINESS                     10. RASH
 5. NAUSEA,VOMITING                11. OTHER SIGN/SYMPTOM
 6. DIARRHEA
Enter from the list above :  7

The following is the list of reported signs/symptoms for this reaction:

          These reactions were entered by another user:
     Signs/Symptoms
-------------------------------------------------------------------------------
     HIVES
     RASH


Select Action (A)DD OR <RET>: <Enter>

Patient died?: N  NO
Reaction treated with RX drug?: N  NO
Life Threatening illness?: N  NO
Required hospitalization?: N  NO
Prolonged Hospitalization?: N  NO
Resulted in permanent disability?: N  NO
Is this event a Congenital Anomaly?: N  NO
Did this event require intervention to prevent impairment/damage?: N  NO

THIS PATIENT HAS NO LAB TEST ON FILE FOR THIS ADVERSE REACTION REPORT
Select Action (A/D/E): ADD

View Tx/Test from: JUN 30, 2004// <Enter>   (JUN 30, 2004)
To: JUN 30, 2004//T  (JUL 07, 2004)

LAB TEST:
   Collection DT   Test Name           Specimen     Results         Hi/Low

     THERE IS NO LAB DATA FOR THIS PATIENT FOR THIS DATE RANGE.
Select TEST: ??

     You may enter a new RELEVANT TEST/LAB DATA, if you wish
Select TEST: ??
Choose from:
1,25-DIHYDROXYVIT D3
1/2HR LTT
1/2Hr.GTT
1/2Hr.GTT (URINE)
11-DEOXYCORTISOL
17-HYDROXYCORTICOSTEROIDS
17-HYDROXYPROGESTERONE
17-KETOGENIC STEROIDS
17-KETOSTEROIDS,TOTAL
1HR LTT
1Hr.GTT
1Hr.GTT (URINE)
25 OH VITAMIN D
2HR LTT
2Hr.GTT
2Hr.GTT (URINE)
```

```
3HR LTT
3Hr.GTT
3Hr.GTT (URINE)
4Hr.GTT
4Hr.GTT (URINE)
^
Select TEST: 1/2Hr.GTT (URINE)
  Are you adding '1/2Hr.GTT (URINE)' as a new TEST (the 1ST for this ADVERSE REA
CTION REPORTING)? No// Y (Yes)
  RESULTS: ??
        This field will contain the results for the particular test.

  RESULTS: Enter results here
  COLLECTION D/T: t  (JUL 07, 2004)
Select TEST: <Enter>

This patient has the following Test selected:
TEST/TX                          RESULTS                        DRAW DATE/TIME
1)   1/2Hr.GTT (URINE)           Enter results here             07/07/04
Select Action (A/D/E): <Enter>

Indicate which FDA Report Sections to be completed:
1.  Reaction Information
2.  Suspect Drug(s) Information
3.  Concomitant Drugs and History
4.  Manufacturer Information
5.  Initial Reporter
Choose number(s) of sections to be edited:  (1-5): <Enter>
```

Enter/Edit P&T Committee Data

This option allows you to edit P&T data. It allows for the evaluation of a suspected Drug Reaction (ADR) by a qualified individual (e.g., clinical pharmacist, clinical pharmacologist), other than the attending physician. You can also track a report to see if it has been sent to the FDA or manufacturer.

```
Select FDA Enter/Edit Menu Option: 2  Enter/Edit P&T Committee Data

Select PATIENT NAME: ARTPATIENT,ONE     2-22-42    666000111     YES     ACTIVE DUTY
 Enrollment Priority:            Category: NOT ENROLLED  End Date: 07/06/2004

Select CAUSATIVE AGENT: AMOXICILLIN,PATIENT  ARTPATIENT,ONE  2-22-42  666000111
YES     ACTIVE DUTY
 Enrollment Priority:            Category: NOT ENROLLED  End Date: 07/06/2004
       AMOXICILLIN
Select date reaction was OBSERVED (Time Optional):  JUNE 30, 2004  (JUN 30, 2004)
JUN 30, 2004  (JUN 30, 2004)
  Are you adding 'JUN 30, 2004' as
    a new ADVERSE REACTION REPORTING? No// Y  (Yes)

P&T Report Completion
Serious ADR?: Y  YES
ADR related to new drug? (Marketed within the last 2 yrs.): N  NO
Unexpected ADR?: Y  YES
ADR related to therapeutic failure?: N  NO
Dose related?: N  NO
P&T ACTION FDA REPORT: ??
        This field indicates if the P&T committee determined whether to send
        the report to FDA.

     Choose from:
       y        YES
       n        NO
P&T ACTION FDA REPORT: N  NO
P&T ACTION MFR REPORT: N  NO

ADDENDUM:
  1> <Enter>

Select PATIENT NAME: <Enter>
```

P&T Committee Menu

The Patient & Therapeutic (P&T) Committee menu should be given to the P&T Committee members of Adverse Reaction Tracking, as designated by the site. The options on this menu allow you to edit P&T data and print FDA data. It allows for the evaluation of a suspected ADR by a qualified individual (e.g., clinical pharmacist, clinical pharmacologist) other than the attending physician, as specified in Section 5.a.(2).(d) of Directive 10-92-070.

1. Enter/Edit P&T Committee Data
2. Enter/Edit FDA Report Data
3. Reports Menu ...

Enter/Edit P&T Committee Data

This option allows you to edit P&T data. It allows for the evaluation of a suspected Advanced Drug Reaction (ADR) by a qualified individual (e.g., clinical pharmacist, clinical pharmacologist), other than the attending physician.

```
Select FDA Enter/Edit Menu Option: 2  Enter/Edit P&T Committee Data

Select PATIENT NAME: ARTPATIENT,ONE     2-22-42    666000111    YES     ACTIVE DUTY
 Enrollment Priority:            Category: NOT ENROLLED  End Date: 07/06/2004

Select CAUSATIVE AGENT: AMOXICILLIN,PATIENT ARTPATIENT,ONE     666000111     YES
ACTIVE DUTY
 Enrollment Priority:            Category: NOT ENROLLED  End Date: 07/06/2004
       AMOXICILLIN
Select date reaction was OBSERVED (Time Optional):  JUNE 30, 2004  (JUN 30, 2004)
JUN 30, 2004  (JUN 30, 2004)
  Are you adding 'JUN 30, 2004' as
    a new ADVERSE REACTION REPORTING? No// Y  (Yes)

P&T Report Completion
Serious ADR?: Y  YES
ADR related to new drug? (Marketed within the last 2 yrs.): N  NO
Unexpected ADR?: Y  YES
ADR related to therapeutic failure?: N  NO
Dose related?: N  NO
P&T ACTION FDA REPORT: ??
        This field indicates if the P&T committee determined whether to send
        the report to FDA.

     Choose from:
       y        YES
       n        NO
P&T ACTION FDA REPORT: N  NO
P&T ACTION MFR REPORT: N  NO

ADDENDUM:
  1> <Enter>

Select PATIENT NAME: <Enter>
```

Enter/Edit FDA Report Data

This option allows users to enter and edit FDA-related data concerning an adverse reaction.

There are five sections to the FDA Report. Fields for Reaction Information (1) are shown in the example. Sections 2-5 are discussed below.

For Suspect Drug(s) Information (2) of the data entry, you may enter/edit the name of a suspect agent for the observed reaction, the daily dose given, route of administration, how the drug was given (SIG Code), the start and stop dates that it was administered, the name of the manufacturer, lot number, number of previous doses given, the last fill date, the drug's expiration date, the National Drug Code number and the indication/reason for the drug's use.

In the Concomitant Drugs and History section (3), you may enter/edit information about the drugs that the patient was taking at the time of the reaction. This includes the name of the drug, the start/stop dates of administration, the last fill date, and how the drug was given (SIG Code). You can also enter a word-processing-type response to indicate any other related history for this drug.

In the Manufacturer Information section (4), you may enter/edit data concerning a manufacturer that should be notified, including the name of the manufacturer, address, the IND/NDA (Investigational New Drug/New Drug Application) number, the manufacturer's control number, the date the drug was received by the manufacturer, the source of the report (i.e., Health Professional), whether the 15 day report was completed and the type of the report (i.e., Initial).

The Initial Reporter (5) section allows you to enter/edit data concerning the person filling out the report, including name, address, phone number, whether the reporter is a health care provider, whether the name of the reporter should be disclosed to the manufacturer, and the reporter's occupational title.

```
Select FDA Enter/Edit Menu Option: 1  Enter/Edit FDA Report Data

Select PATIENT NAME: ARTPATIENT,ONE     2-22-42    666000111    YES     ACTIVE DUTY
 Enrollment Priority:            Category: NOT ENROLLED  End Date: 07/06/2004

Select CAUSATIVE AGENT: FLOXURIDINE, PATIENT  ARTPATIENT,ONE   2-22-42  666000111
YES     ACTIVE DUTY
 Enrollment Priority:            Category: NOT ENROLLED  End Date: 07/06/2004
       FLOXURIDINE
Select date reaction was OBSERVED (Time Optional):  6/30/04  (JUN 30, 2004)
         ...OK? Yes// <Enter>  (Yes)

Indicate which FDA Report Sections to be completed:
1.  Reaction Information
2.  Suspect Drug(s) Information
3.  Concomitant Drugs and History
4.  Manufacturer Information
5.  Initial Reporter
Choose number(s) of sections to be edited:  (1-5): 1

The following is the list of reported signs/symptoms for this reaction:
          These reactions were entered by another user:
     Signs/Symptoms
-------------------------------------------------------------------------------
     RASH
```

```
Select Action (A)DD OR <RET>: A

The following are the top ten most common signs/symptoms:
 1. CHILLS                          7. HIVES
 2. ITCHING,WATERING EYES           8. DRY MOUTH
 3. HYPOTENSION                     9. DRY NOSE
 4. DROWSINESS                     10. RASH
 5. NAUSEA,VOMITING                11. OTHER SIGN/SYMPTOM
 6. DIARRHEA
Enter from the list above :  7

The following is the list of reported signs/symptoms for this reaction:

          These reactions were entered by another user:
     Signs/Symptoms
-------------------------------------------------------------------------------
     HIVES
     RASH


Select Action (A)DD OR <RET>: <Enter>

Patient died?: N  NO
Reaction treated with RX drug?: N  NO
Life Threatening illness?: N  NO
Required hospitalization?: N  NO
Prolonged Hospitalization?: N  NO
Resulted in permanent disability?: N  NO
Is this event a Congenital Anomaly?: N  NO
Did this event require intervention to prevent impairment/damage?: N  NO

THIS PATIENT HAS NO LAB TEST ON FILE FOR THIS ADVERSE REACTION REPORT
Select Action (A/D/E): ADD

View Tx/Test from: JUN 30, 2004// <Enter>   (JUN 30, 2004)
To: JUN 30, 2004//T  (JUL 07, 2004)

LAB TEST:
   Collection DT   Test Name           Specimen     Results         Hi/Low

     THERE IS NO LAB DATA FOR THIS PATIENT FOR THIS DATE RANGE.
Select TEST: ??

     You may enter a new RELEVANT TEST/LAB DATA, if you wish
Select TEST: ??
Choose from:
1,25-DIHYDROXYVIT D3
1/2HR LTT
1/2Hr.GTT
1/2Hr.GTT (URINE)
11-DEOXYCORTISOL
17-HYDROXYCORTICOSTEROIDS
17-HYDROXYPROGESTERONE
17-KETOGENIC STEROIDS
17-KETOSTEROIDS,TOTAL
1HR LTT
1Hr.GTT
1Hr.GTT (URINE)
25 OH VITAMIN D
2HR LTT
2Hr.GTT
```

```
2Hr.GTT (URINE)
3HR LTT
3Hr.GTT
3Hr.GTT (URINE)
4Hr.GTT
4Hr.GTT (URINE)
^
Select TEST: 1/2Hr.GTT (URINE)
  Are you adding '1/2Hr.GTT (URINE)' as a new TEST (the 1ST for this ADVERSE REA
CTION REPORTING)? No// Y
  (Yes)
  RESULTS: ??
        This field will contain the results for the particular test.

  RESULTS: Enter results here
  COLLECTION D/T: t  (JUL 07, 2004)
Select TEST: <Enter>

This patient has the following Test selected:
TEST/TX                          RESULTS                        DRAW DATE/TIME
1)   1/2Hr.GTT (URINE)           Enter results here             07/07/04
Select Action (A/D/E): <Enter>

Indicate which FDA Report Sections to be completed:
1.  Reaction Information
2.  Suspect Drug(s) Information
3.  Concomitant Drugs and History
4.  Manufacturer Information
5.  Initial Reporter
Choose number(s) of sections to be edited:  (1-5): <Enter>
```

Reports Menu (P&T)

This option is the menu of all reports that the Pharmacy and Therapeutics Committee can print. To view data for options 1 thru 12 below, please see the Reports Menu under the Verifier Menu (see Table of Contents for correct page numbers.) For options 13 thru 19, please continue on the following pages.

1. Print an FDA Report for a Patient
2. Print all FDA Events within D/T range
3. Print Patient FDA Exception Data
4. Print all FDA Exceptions within a D/T range
5. Patient Allergies Not Signed Off
6. Print Patient Reaction Data
7. Active Listing of Patient Reactions
8. List by Location of Undocumented Allergies
9. List Autoverified Reaction Data
10. List by Location Not Verified Reactions
11. List by Location and Date all Sign Reactions
12. List FDA Data by Report Date
13. List of Fatal Reaction Over a Date Range
14. Print Summary of Outcomes
15. Frequency Distribution of Causative Agents
16. Frequency Distribution of Drug Classes
17. Total Reported Reactions Over a Date Range
18. P&T Committee ADR Outcome Report
19. P&T Committee ADR Report

List of Fatal Reaction Over a Date Range

This option lists all fatal adverse drug reactions over a selected date range.

The header of the report contains the name of the report, the date range selected, and the date that the report was printed. The body of the report contains the name of the patient, the last four digits of the patient's SSN, the date of the reaction, the name of the related reaction, and the date the patient died.

```
Select Reports Menu Option: 13 List of Fatal Reaction over a Date Range
Select an Observed date range for this report.
Enter Start Date: T-365 (JAN 30, 1995)
Enter Ending Date: T (JAN 30, 1996)

DEVICE: HOME// <Enter> HOME

Report Date: Jan 30, 1996 Page: 1
               List of Fatal Reaction over a date range
                   From: 1/30/95 To: 1/30/96

Patient                Dates      Related Reaction       Date Died
------------------------------------------------------------------------------
ARTPATIENT,TWO (T0112) 2/8/95       TYLOXAPOL              2/9/95

Enter  RETURN to continue or '^' to exit: < Enter>
```

Print Summary of Outcomes

This option prints a summary report of patient outcomes for a selected date range.

The header of the report contains the name of the report, the date range selected, and the date the report was run. The body of the report contains the outcome and number of times a user answered with a "Yes, No or No Response" to the outcome question. A total is printed for each column of responses. The number of records processed is printed, also. The sum of each Yes, No, and No Response column equals the number of records processed (e.g., 3+38+249=290).

```
Select Reports Menu Option: 14  Print Summary of Outcomes
Select an Observed date range for this report.
Enter Start Date: T-365  (JUL 08, 2003)
Enter Ending Date: T  (JUL 07, 2004)


DEVICE: HOME// <Enter>  ANYWHERE

Report Date: Jul 07, 2004                                      Page: 1
                            Summary of Outcomes
                         From: 7/8/03 To: 7/7/04
                                          Yes          No        No Response
-------------------------------------------------------------------------------
                    Patients that Died:              | 2       | 50
       Reactions treated with RX drugs:              | 2       | 50
              Life Threatening illness:              | 2       | 50
                  Required ER/MD visit:              |         | 52
              Required hospitalization:              | 2       | 50
             Prolonged Hospitalization:              | 2       | 50
      Resulted in permanent disability:              | 2       | 50
                    Patient recovered:               |         | 52
                  Congenital Anomaly:                | 2       | 50
                Required intervention:               | 2       | 50
                                        ---------------------------------------
                                Totals:   0          | 16      | 504

                      Total number of records processed 52
Enter RETURN to continue or '^' to exit: ^
```

Frequency Distribution of Causative Agents

This option prints a report of the frequency distribution of causative agents for a date range selected by you.

The header of the report contains the name of the report, the date range selected by you and the date that the report was run. The body of the report contains the name of the causative agent and the number of times it was reported within the date range.

```
Select Reports Menu Option: 15  Frequency Distribution of Causative Agents
Select an Observed date range for this report.
Enter Start Date: T-365  (JUL 08, 2003)
Enter Ending Date: T  (JUL 07, 2004)

DEVICE: HOME// <Enter>  ANYWHERE
Report Date: Jul 07, 2004                                        Page: 1
                    Frequency Distribution of Causative Agents
                         From: 7/8/03 To: 7/7/04
Causative Agents                  Number
------------------------------------------------------------------------------
                     CHOCOLATE :    6
                   AMOXICILLIN :    3
                          DUST :    3
                    FILGRASTIM :    3
                    PENICILLIN :    3
                        ZANTAC :    3
                     ACYCLOVIR :    2
               ANTIRABIES SERUM :    2
                  BACAMPICILLIN :    2
                     RANITIDINE :    2
                         SHRIMP :    2
                   STRAWBERRIES :    2
                      ZANAMIVIR :    2
                     AMPICILLIN :    1
                       BENADRYL :    1
    BETA-LACTAM ANTIMICROBIALS :    1
Enter RETURN to continue or '^' to exit:
Report Date: Jul 07, 2004                                        Page: 2
                    Frequency Distribution of Causative Agents
                         From: 7/8/03 To: 7/7/04
Causative Agents                  Number
------------------------------------------------------------------------------
                       CAFFEINE :    1
                  CORICIDIN TAB :    1
         EYE WASHES/LUBRICANTS :    1
                   FLOXURIDINE :    1
                  FORMALDEHYDE :    1
                    FORMOTEROL :    1
                    GREEN BEAN :    1
                        IODINE :    1
  LEAD ACETATE PURIFIED POWDER :    1
                     MENADIONE :    1
                       PARABEN :    1
                    PEANUT OIL :    1
     POLLEN ALLERGENIC EXTRACT :    1
         SHILEY TRACH TUBE CFS :    1

                     Total number of records processed 52
Enter RETURN to continue or '^' to exit:
```

Frequency Distribution of Drug Classes

This option prints a report of the frequency distribution of drug classes for a selected date range.

The header of the report contains the name of the report, the date range selected, and the date the report was run. The body of the report contains the drug classification name followed by its code in parentheses and the number of times it was reported during the selected date range.

```
Select Reports Menu Option: 16  Frequency Distribution of Drug Classes
Select an Observed date range for this report.
Enter Start Date: T-365  (JUL 08, 2003)
Enter Ending Date: T  (JUL 07, 2004)


DEVICE: HOME//   ANYWHERE

Report Date: Jul 07, 2004                                      Page: 1
                    Frequency Distribution of Drug Classes
                         From: 7/8/03 To: 7/7/04
Drug Class                              Number
------------------------------------------------------------------------------
 PENICILLINS,AMINO DERIVATIVES (AM052) :    6
                    ANTIVIRALS (AM800) :    4
         HISTAMINE ANTAGONISTS (GA301) :    4
      BLOOD FORMATION PRODUCTS (BL400) :    3
PENICILLIN-G RELATED PENICILLI (AM051) :    3
 DERMATOLOGICALS,TOPICAL OTHER (DE900) :    2
                IMMUNE SERUMS (IM400) :    2
             ANTIVIRAL,TOPICAL (DE103) :    2
    BETA-LACTAM ANTIMICROBIALS (AM100) :    1
ANTINEOPLASTICS,ANTIMETABOLITE (AN300) :    1
     ANTISEPTICS/DISINFECTANTS (AS000) :    1
    IMMUNOLOGICAL AGENTS,OTHER (IM900) :    1
         EYE WASHES/LUBRICANTS (OP500) :    1
  PHARMACEUTICAL AIDS/REAGENTS (PH000) :    1
BRONCHODILATORS,SYMPATHOMIMETI (RE102) :    1
                SUPPLIES,OTHER (XA900) :    1
   ANTIHISTAMINES,ETHANOLAMINE (AH102) :    1
                     MENADIOL (VT701) :    1

                     Total number of records processed 52
Enter RETURN to continue or '^' to exit:
```

Total Reported Reactions Over a Date Range

This option prints a report of the total number of reported reactions for a selected date range.

The header of the report contains the title of the report and when it was run. The body of report contains the total number of actions reported for the date range listed.

```
Select Reports Menu Option: 17  Total Reported Reactions Over a Date Range
Select an Observed date range for this report.
Enter Start Date: T-365  (JUL 08, 2003)
Enter Ending Date: T  (JUL 07, 2004)


DEVICE: HOME//   ANYWHERE

Report Date: Jul 07, 2004                                      Page: 1
                                  Reported Reactions
------------------------------------------------------------------------------
                   Total Number of Reported Reactions: 52
                            From: 7/8/03   To: 7/7/04
Enter RETURN to continue or '^' to exit:
```

P&T Committee ADR Outcome Report

This option displays a list of Adverse Drug Reactions (ADRs) over a date range and a summary of the listed outcomes for those ADRs. The header of this report contains the name of the report, the date range selected, and the date the report was run. The body of the report contains the date the reaction was observed, the causative agent, the signs and symptoms, whether the reaction required treatment (Req. Tx), whether the reaction required hospitalization (Req. Hosp), whether the reaction caused a permanent disability (Dis.), and did the patient die as a result of the reaction.

```
Select Reports Menu Option: 18  P&T Committee ADR Outcome Report
Select an Observed date range for this report.
Enter Start Date: T-365  (JUL 08, 2003)
Enter Ending Date: T  (JUL 07, 2004)


DEVICE: HOME// <Enter>  ANYWHERE

Report Date: Jul 07, 2004                                      Page: 1
                      P&T Committee ADR Outcome Report
                         From: 7/8/03 To: 7/7/04
-------------------------------------------------------------------------------
Obsv.   |                                |                  |Req.|Req.|    |
Date    |Causative agent-Pat. ID         |Sign/Symptoms     |Tx  |Hosp|Dis.|Death
-------------------------------------------------------------------------------
 7/16/03|BETA-LACTAM ANTIMICROB-C4573     |HYPOTENSION       |    |    |    |
        |                                |ANAPHYLAXIS       |    |    |    |
        |                                |                  |    |    |    |
 7/16/03|RANITIDINE-F8839                |CHILLS            |    |    |    |
        |                                |                  |    |    |    |
 7/30/03|PARABEN-F0388                   |                  |    |    |    |
        |                                |                  |    |    |    |
 7/31/03|CHOCOLATE-W0167                 |                  |    |    |    |
        |                                |                  |    |    |    |
  8/1/03|ACYCLOVIR-A2222                 |CHILLS            |    |    |    |
        |                                |                  |    |    |    |
  8/1/03|BENADRYL-F0388                  |NAUSEA,VOMITING   |    |    |    |
        |                                |CHILLS            |    |    |    |
        |                                |                  |    |    |    |
Enter RETURN to continue or '^' to exit:

Report Date: Jul 07, 2004                                      Page: 2
                      P&T Committee ADR Outcome Report
                         From: 7/8/03 To: 7/7/04
-------------------------------------------------------------------------------
Obsv.   |                                |                  |Req.|Req.|    |
Date    |Causative agent-Pat. ID         |Sign/Symptoms     |Tx  |Hosp|Dis.|Death
-------------------------------------------------------------------------------
 8/19/03|CHOCOLATE-B5545                 |CHILLS            |    |    |    |
        |                                |                  |    |    |    |
 8/21/03|DUST-J8910                      |CHILLS            |    |    |    |
        |                                |                  |    |    |    |
 8/27/03|DUST-W1321                      |CHILLS            |    |    |    |
        |                                |                  |    |    |    |
 8/27/03|SHILEY TRACH TUBE CFS-S4423     |CHILLS            |    |    |    |
        |                                |                  |    |    |    |
 8/28/03|CHOCOLATE-W1321                 |DRY NOSE          |    |    |    |
        |                                |                  |    |    |    |
 8/28/03|GREEN BEAN-F8828                |CHILLS            |    |    |    |
        |                                |                  |    |    |    |
 8/28/03|STRAWBERRIES-A2222              |CHILLS            |    |    |    |
        |                                |                  |    |    |    |
```

```
Enter RETURN to continue or '^' to exit:

Report Date: Jul 07, 2004                                        Page: 3
                      P&T Committee ADR Outcome Report
                         From: 7/8/03 To: 7/7/04
-------------------------------------------------------------------------------
Obsv.   |                              |                    |Req.|Req.|    |
Date    |Causative agent-Pat. ID       |Sign/Symptoms       |Tx  |Hosp|Dis.|Death
-------------------------------------------------------------------------------
 8/28/03|ZANTAC-A2222                  |ANXIETY             |    |    |    |
        |                              |                    |    |    |    |
 8/28/03|ZANTAC-W1321                  |ANXIETY             |    |    |    |
        |                              |                    |    |    |    |
 9/17/03|POLLEN ALLERGENIC EXTR-B8831  |HYPOTENSION         |    |    |    |
        |                              |                    |    |    |    |
 11/4/03|CAFFEINE-B8831                |RASH                |    |    |    |
        |                              |                    |    |    |    |
 1/19/04|EYE WASHES/LUBRICANTS-A4321   |DROWSINESS          |    |    |    |
        |                              |                    |    |    |    |
 1/27/04|DUST-N5423                    |CHILLS              |    |    |    |
        |                              |                    |    |    |    |
 1/30/04|CHOCOLATE-B1996               |CHILLS              |    |    |    |
        |                              |                    |    |    |    |
Enter RETURN to continue or '^' to exit:

Report Date: Jul 07, 2004                                        Page: 4
                      P&T Committee ADR Outcome Report
                         From: 7/8/03 To: 7/7/04
-------------------------------------------------------------------------------
Obsv.   |                              |                    |Req.|Req.|    |
Date    |Causative agent-Pat. ID       |Sign/Symptoms       |Tx  |Hosp|Dis.|Death
-------------------------------------------------------------------------------
 1/30/04|CHOCOLATE-Z3431               |CHILLS              |    |    |    |
        |                              |                    |    |    |    |
  2/2/04|PENICILLIN-L7727              |ITCHING,WATERING EY |    |    |    |
        |                              |                    |    |    |    |
  2/2/04|ZANTAC-N5423                  |CHILLS              |    |    |    |
        |                              |                    |    |    |    |
 2/12/04|AMOXICILLIN-Z4255             |CHILLS              |    |    |    |
        |                              |DRY MOUTH           |    |    |    |
        |                              |                    |    |    |    |
 2/18/04|FILGRASTIM-Z3333              |CHILLS              |    |    |    |
        |                              |                    |    |    |    |
 2/18/04|FILGRASTIM-Z3333              |CHILLS              |    |    |    |
        |                              |ITCHING,WATERING EY |    |    |    |
        |                              |                    |    |    |    |
Enter RETURN to continue or '^' to exit:

Report Date: Jul 07, 2004                                        Page: 5
                      P&T Committee ADR Outcome Report
                         From: 7/8/03 To: 7/7/04
-------------------------------------------------------------------------------
Obsv.   |                              |                    |Req.|Req.|    |
Date    |Causative agent-Pat. ID       |Sign/Symptoms       |Tx  |Hosp|Dis.|Death
-------------------------------------------------------------------------------
 2/19/04|AMOXICILLIN-Z4255             |HYPOTENSION         |    |    |    |
        |                              |                    |    |    |    |
 2/19/04|PENICILLIN-Z4255              |CHILLS              |    |    |    |
        |                              |                    |    |    |    |
 2/26/04|FILGRASTIM-Z6414              |CHILLS              |    |    |    |
        |                              |FREE TEXT           |    |    |    |
        |                              |                    |    |    |    |
 2/26/04|MENADIONE-Z8322               |CHILLS              |    |    |    |
```

```
        |                              |FREE TEXT          |    |    |    |
        |                              |                   |    |    |    |
 2/27/04|BACAMPICILLIN-B8849           |DIARRHEA           |    |    |    |
        |                              |                   |    |    |    |
 2/27/04|BACAMPICILLIN-Z4255           |DIARRHEA           |    |    |    |
        |                              |                   |    |    |    |
Enter RETURN to continue or '^' to exit:

Report Date: Jul 07, 2004                                          Page: 6
                     P&T Committee ADR Outcome Report
                        From: 7/8/03 To: 7/7/04
-------------------------------------------------------------------------------
Obsv.   |                              |                   |Req.|Req.|    |
Date    |Causative agent-Pat. ID       |Sign/Symptoms      |Tx  |Hosp|Dis.|Death
-------------------------------------------------------------------------------
 3/16/04|CHOCOLATE-A0150               |DROWSINESS         |    |    |    |
        |                              |NAUSEA,VOMITING    |    |    |    |
        |                              |DIARRHEA           |    |    |    |
        |                              |                   |    |    |    |
 3/16/04|PEANUT OIL-A0150              |HYPOTENSION        |    |    |    |
        |                              |DIARRHEA           |    |    |    |
        |                              |DRY MOUTH          |    |    |    |
        |                              |                   |    |    |    |
 3/17/04|CORICIDIN TAB-A4321           |CHILLS             |    |    |    |
        |                              |HYPOTENSION        |    |    |    |
        |                              |                   |    |    |    |
  4/2/04|AMPICILLIN-A8989              |CHILLS             |    |    |    |
        |                              |                   |    |    |    |
  4/5/04|STRAWBERRIES-A8989            |CHILLS             |    |    |    |
Enter RETURN to continue or '^' to exit:

Report Date: Jul 07, 2004                                          Page: 7
                     P&T Committee ADR Outcome Report
                        From: 7/8/03 To: 7/7/04
-------------------------------------------------------------------------------
Obsv.   |                              |                   |Req.|Req.|    |
Date    |Causative agent-Pat. ID       |Sign/Symptoms      |Tx  |Hosp|Dis.|Death
-------------------------------------------------------------------------------
        |                              |                   |    |    |    |
 4/30/04|PENICILLIN-D6616              |HIVES              |    |    |    |
        |                              |                   |    |    |    |
 5/20/04|IODINE-B8847                  |DRY NOSE           |    |    |    |
        |                              |                   |    |    |    |
 5/20/04|LEAD ACETATE PURIFIED -Z9558  |HIVES              |    |    |    |
        |                              |                   |    |    |    |
  6/8/04|ANTIRABIES SERUM-H2591        |CHILLS             |    |    |    |
        |                              |                   |    |    |    |
  6/8/04|ANTIRABIES SERUM-A0999        |CHILLS             |    |    |    |
        |                              |                   |    |    |    |
 6/15/04|SHRIMP-T8828                  |HIVES              |    |    |    |
        |                              |                   |    |    |    |
 6/21/04|ACYCLOVIR-Z9558               |HYPOTENSION        |    |    |    |
Enter RETURN to continue or '^' to exit:

Report Date: Jul 07, 2004                                          Page: 8
                     P&T Committee ADR Outcome Report
                        From: 7/8/03 To: 7/7/04
-------------------------------------------------------------------------------
Obsv.   |                              |                   |Req.|Req.|    |
Date    |Causative agent-Pat. ID       |Sign/Symptoms      |Tx  |Hosp|Dis.|Death
-------------------------------------------------------------------------------
        |                              |                   |    |    |    |
 6/21/04|RANITIDINE-Z9558              |CHILLS             |    |    |    |
```

```
        |                                |                    |    |    |    |
 6/21/04|ZANAMIVIR-Z9558                 |CHILLS              |    |    |    |
        |                                |                    |    |    |    |
 6/21/04|ZANAMIVIR-Z9558                 |CHILLS              |    |    |    |
        |                                |HYPOTENSION         |    |    |    |
        |                                |                    |    |    |    |
 6/28/04|SHRIMP-A4321                    |RASH                |    |    |    |
        |                                |                    |    |    |    |
 6/30/04|AMOXICILLIN-A4321               |                    |    |    |    |
        |                                |                    |    |    |    |
 6/30/04|FLOXURIDINE-A4321               |RASH                |    |    |    |
        |                                |HIVES               |    |    |    |
Enter RETURN to continue or '^' to exit:

Report Date: Jul 07, 2004                                        Page: 9
                      P&T Committee ADR Outcome Report
                         From: 7/8/03 To: 7/7/04
-------------------------------------------------------------------------------
Obsv.   |                                |                    |Req.|Req.|    |
Date    |Causative agent-Pat. ID         |Sign/Symptoms       |Tx  |Hosp|Dis.|Death
-------------------------------------------------------------------------------
        |                                |                    |    |    |    |
 6/30/04|FORMALDEHYDE-A4321              |RASH                |    |    |    |
        |                                |                    |    |    |    |
 6/30/04|FORMOTEROL-A4321                |RASH                |    |    |    |
        |                                |                    |    |    |    |
Enter RETURN to continue or '^' to exit:
```

P&T Committee ADR Report

This option displays a list of Adverse Drug Reactions (ADRs) over a date range. The Sign/Symptoms, Mechanism, Severity, and Comments are displayed for each ADR. This report should be queued to a printer that has a column width of 132 characters. The header of the report contains the name of the report, the date range selected, and the date the report was run. The body of the report contains the date the reaction was observed, the causative agent, the signs and symptoms, the mechanism of the adverse reaction (i.e., A=Allergy, P=Pharmacologic, and U=Unknown), and any comments entered. The comments are identified by category (i.e., Observer, Verifier or Entered in Error).

```
Select Reports Menu Option: 19 P&T Committee ADR Report
Select an Observed date range for this report.
Enter Start Date: 1/1/96 (JAN 01, 1996)
Enter Ending Date: 1/31/96 (JAN 31, 1996)

This report required a 132 column printer.

DEVICE: HOME// QUEUE TO PRINT ON
DEVICE: HOME// SELECT APPROPRIATE PRINTER COMPUTER ROOM

Requested Start Time: NOW// < Enter> (FEB 06, 1996@11:23:22)

Request queued...
                    Report Date: Feb 06, 1996 Page: 1
                       P&T Committee ADR Report
                       From: 1/1/96 To: 1/31/96
-------------------------------------------------------------------------------
Obsv.  |                                          |  |ADR |ADR |
Date   |Causative agent         |Sign/Symptoms    |Mech |Svr.|Comments
-------------------------------------------------------------------------------
1/1/96 |PSUEDOEPHEDRINE         |HIVES            | U   |    |OBSERVER COMMENTS:
       |                        |ITCHING,WATERING EY|   |    |THIS IS A TEST
       |                        |NAUSEA,VOMITING  |     |    |
       |                        |DIARRHEA         |     |    |
       |                        |ANXIETY          |     |    |
       |                        |CHILLS           |     |    |
       |                        |DROWSINESS       |     |    |
       |                        |DRY MOUTH        |     |    |
       |                        |HYPOTENSION      |     |    |
1/8/96 |SALT SUBSTITUTE         |SWELLING (NON-SPECI| U   |MOD.|OBSERVER COMMENTS:
       |                        |NAUSEA,VOMITING  |     |    |Patient's swelling
       |                        |                 |     |    |was observed by the
       |                        |                 |     |    | nurse.
1/8/96 |FUZZEL                  |HIVES            | U   |    |OBSERVER COMMENTS:
       |                        |ITCHING,WATERING EY|   |    |
       |                        |NAUSEA,VOMITING  |     |    |
       |                        |DIARRHEA         |     |    |
       |                        |ANXIETY          |     |    |
1/9/96 |POLLEN                  |ITCHING,WATERING EY| U   |MOD.|OBSERVER COMMENTS:
       |                        |                 |     |    |the patient had a
       |                        |                 |     |    |moderate reaction
       |                        |                 |     |    |to some flowers.
1/10/96|ASPIRIN                 |NAUSEA,VOMITING  | U   |    |
       |                        |DRY MOUTH        |     |    |
```

Using ART in CPRS GUI

On Cover Sheet

In the Allergies/Adverse Reactions pane on the Cover Sheet tab, CPRS displays a list of causative agents associated with patients' allergies or adverse reactions. If patients have causative agents listed in this pane, CPRS also displays the word *Allergies* in the Postings pane and the letter **A** (for allergies) on the Postings button. To view more information about allergies or adverse reactions associated with the causative agents listed in the Allergies/Adverse Reactions pane, simply click on the causative agent in which you are interested. CPRS then displays a comprehensive listing of the details associated with this causative agent.

You can obtain less comprehensive information about allergies and adverse reactions by clicking the word *Allergies* in the Postings pane. When you do this, CPRS displays information about the causative agents, severity, and signs/symptoms associated with patients' allergies and adverse reactions.

From the Cover Sheet tab, you can also:

- Enter new allergies
- Mark existing allergies or adverse reactions as having been entered in error
- Enter no-known-allergies (NKA) assessments

Entering Allergies

You can enter a new allergy or adverse reaction from the Cover Sheet tab in either of two ways:

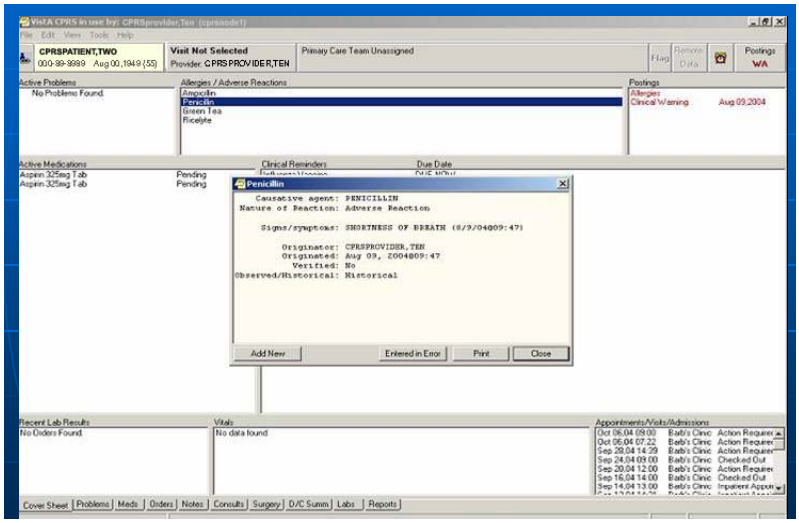
1. Right-click anywhere within the Allergies/Adverse Reactions pane.
2. Click to display more information about a causative agent listed in the Allergies/Adverse Reactions pane.

You can also enter allergies or adverse reactions from the Orders tab. (See "Entering Allergies from the Orders Tab" later in this section of this manual for more information.)

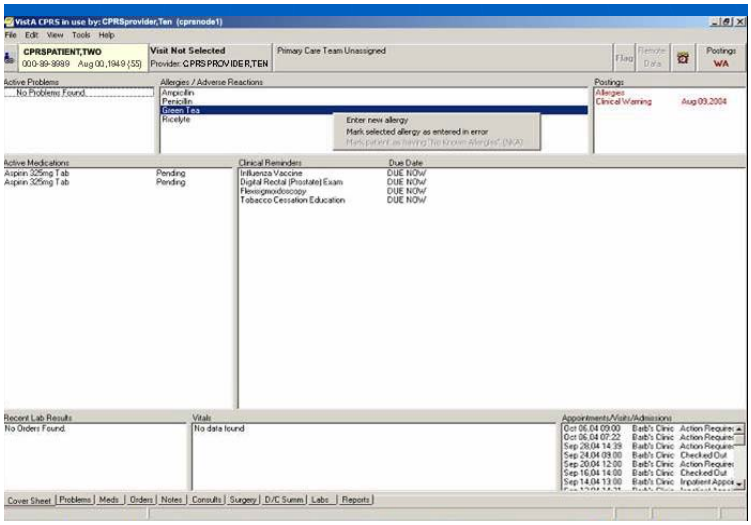
Method One

Follow these steps to enter new allergies using the first of the two methods mentioned above:

1. Move your mouse arrow to a location anywhere within the Allergies/Adverse Reactions pane.
2. Right-click to display a pop-up menu.



3. From this menu, select Enter new allergy. CPRS displays the *Allergy Reactant Lookup* dialog.



4. In the Enter causative agent for Allergy or Adverse Drug Reaction field, type the first three characters (minimum) of the causative agent.
5. Click Search. CPRS displays a list of possible matches.
6. If the causative agent you typed does not match any of the agents currently available for your site, CPRS displays the Causative Agent Not On File dialog, from which you can select one of the following three options:
   a. **Yes**: Use this option to request that the causative agent be added to your site's ALLERGIES file. When you click **Yes**, CPRS displays the *Enter Optional Comments* dialog box, which enables you to type additional comments (optional), such as the signs or symptoms that occurred as a result of contact with this causative agent, or

whether you observed these symptoms firsthand. After you type your comments, click **Continue**. CPRS then sends to members of your site's GMRA Request New Reactant mail group a message that includes the following items:

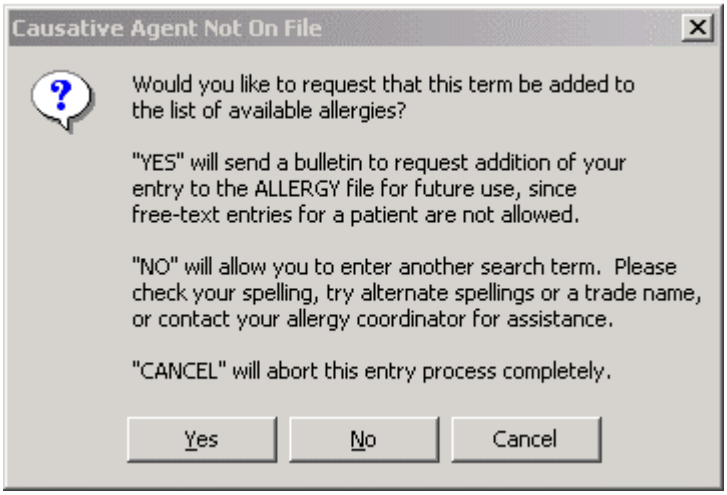
- The causative agent you attempted to enter
- The name of the patient for whom you attempted to make this entry
- Your name, title, and contact information
- Your comments (if any)

Members of your site's GMRA Request New Reactant mail group will review this message and, if appropriate, add the causative agent to your site's ALLERGIES file.

Note: If your site's IRM staff has not yet added members to your site's GMRA Request New Reactant mail group, CPRS displays the following message:

b. No: Clicking No enables you to try an alternate spelling or trade name for your causative agent, or to type another causative agent.

c. Cancel: Use this option if you want to cancel your allergy entry.

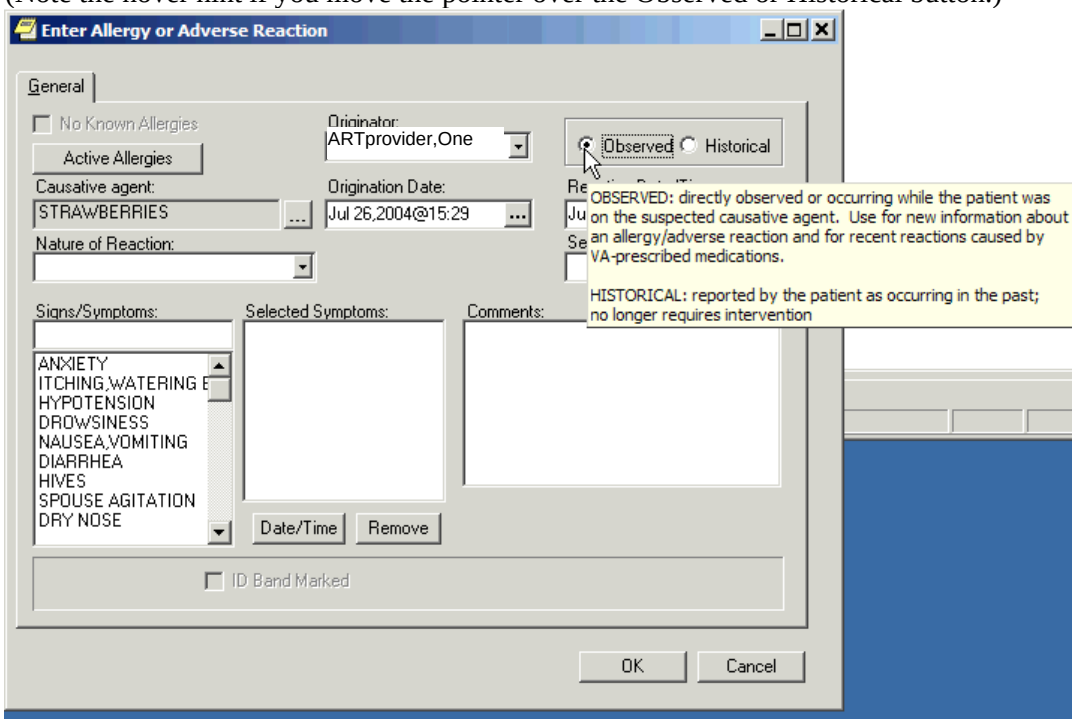


7. If the causative agent you typed matches an agent that is currently available for your site, select the agent. (Click + to expand a heading.)

NOTE: With CPRS GUI 24 or later, you may not add free-text allergies. If you select an item under the "Add new free-text allergy" heading, CPRS displays the *Causative Agent Not On File* dialog box. (See Step 6 above.)

8. Click OK. The *Enter Allergy or Adverse Reaction* dialog appears.

(Note the hover hint if you move the pointer over the Observed or Historical button.)



NOTE: You can view a patient's current allergies or adverse reactions by clicking the Active Allergies button.

9. Using the Originator and Origination Date boxes, select an originator and origination date, respectively. The origination date is system-populated and not editable.
10. Use the Observed or Historical option button to indicate whether the entry is for an observed or historical allergy, respectively. (If you point your mouse at either of these option buttons, CPRS displays a hover hint that defines observed and historical.)

    NOTE: CPRS does not allow you to select future dates for observed allergy/adverse reaction entries.

    NOTE: When you select Observed for a drug reaction, CPRS generates a Progress Note. Once this note is signed by the originator or an administrative update user, the note will be viewable by all users.

11. Use the Nature of Reaction list box to select a mechanism (Allergy, Pharmacological, or Unknown).

    An *allergic* reaction occurs because the patient is sensitive to a causative agent, regardless of the amount the patient is exposed to. A *pharmacologic* (non-allergic) reaction occurs when the patient is sensitive to an agent under certain conditions, such as exposure to a large amount. *Unknown* is provided if you are not sure what Nature of Reaction (mechanism) to enter.

NOTE: Allergies are a subset of adverse reactions. All allergies are adverse reactions, but not all adverse reactions are allergies.

12. If you are entering an observed allergy, use the Reaction Date/Time and Severity boxes to select a reaction date, time, and severity. (The Severity box is not visible for historical allergies. If the Severity box is visible, CPRS displays a **?** button at its side. If you click this button, CPRS displays text explaining severity selections.)
13. Using the Signs/Symptoms box, select one or more signs or symptoms. The signs and symptoms you select appear in the Selected Symptoms pane.
14. To associate a date and time with a symptom (optional), click to select the symptom in the **Selected Symptoms** pane.
15. Click the **Date/Time** button located below the **Selected Symptoms** pane. CPRS displays the **Select Date/Time** dialog, from which you can select the date and time that the symptom first appeared.

    Note: If you mistakenly enter a sign or symptom but have not yet accepted it by selecting OK, select the symptom in the **Selected Symptoms** pane and click the **Remove** button located beneath the pane.
16. Type comments for the allergy in the Comments text box.
17. If you have marked the allergy or adverse reaction on the patient's identification (ID) band (or if you know that someone else has performed this task), select the ID Band Marked checkbox.

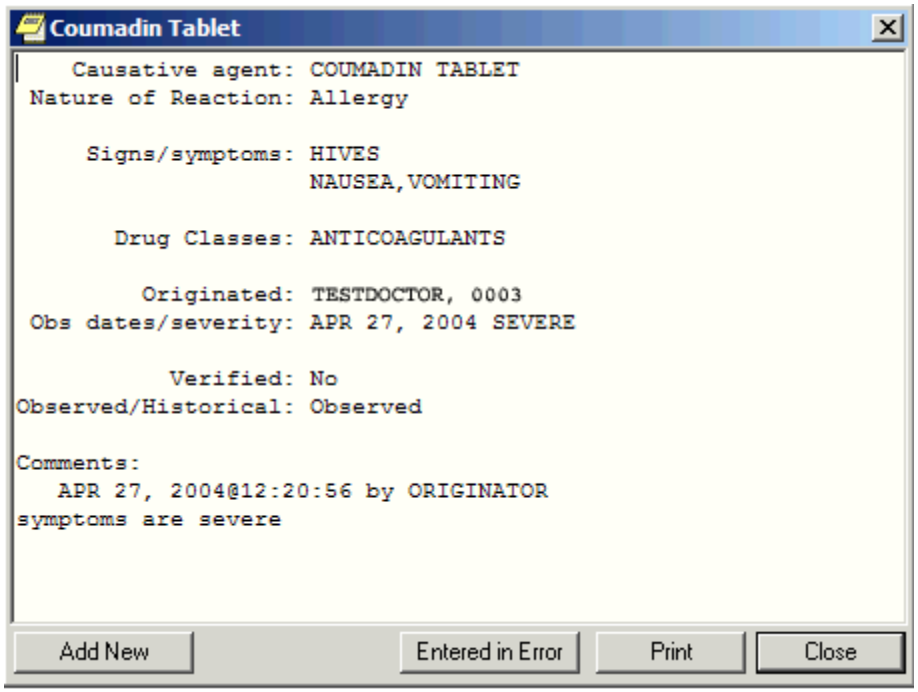
    NOTE: CPRS activates the ID Band Marked checkbox only for inpatients and then only if your site's IRM staff has set a parameter indicating that your site wants to track this information. Depending on whether your IRM staff has set related parameters, if you do not select activated ID Band Marked checkbox, the system may send a bulletin notifying a mail group that the patient's allergy or adverse reaction is not marked on his or her ID band.

18. Click OK. CPRS displays the newly entered causative agent in the Allergies/Adverse Reactions pane. If you click on the causative agent, CPRS displays all of the information you just entered about the associated allergy or adverse reaction. CPRS also displays the letter **A** (for allergies) on the Postings button and the word *Allergies* in the Postings pane. If you click the word *Allergies* in the Postings pane, CPRS displays selected information about the allergy or adverse reaction you just entered.

Method Two

Follow these steps to enter a new allergy using the second of the two methods mentioned above:

1. Click to select a causative agent listed in the Allergies/Adverse Reactions pane. CPRS displays a dialog that includes details about the allergy or adverse reaction associated with the selected causative agent. The dialog also includes four buttons.



2. Click the Add New button. CPRS displays the *Allergy Reactant Lookup* dialog.
3. Follow steps 4 through 17 of the instructions for entering allergies using the first method. CPRS displays the newly entered causative agent in the Allergies/Adverse Reactions pane. If you click on the causative agent, CPRS displays all of the information you just entered about the associated allergy or adverse reaction. CPRS also displays the letter **A** (for allergies) on the Postings button and the word *Allergies* in the Postings pane. If you click the word *Allergies* in the Postings pane, CPRS displays selected information about the allergy or adverse reaction you just entered.

Entering No-Known-Allergies Assessments

You can enter no-known-allergies (NKA) assessments for patients who have no known allergies by taking the following steps:

1. Right-click within the Allergies/Adverse Reactions pane or select the phrase *No Allergy Assessment* within the Allergies/Adverse Reactions pane and then right-click to display a menu.

2. From this menu, select Mark patient as having No Known Allergies (NKA). CPRS displays the *No Known Allergies* dialog.

NOTE: CPRS activates the Mark patient as having No Known Allergies (NKA) menu selection only for patients who have no known allergies. When patients have previously entered allergies, CPRS deactivates this selection.

3. Click **OK**.

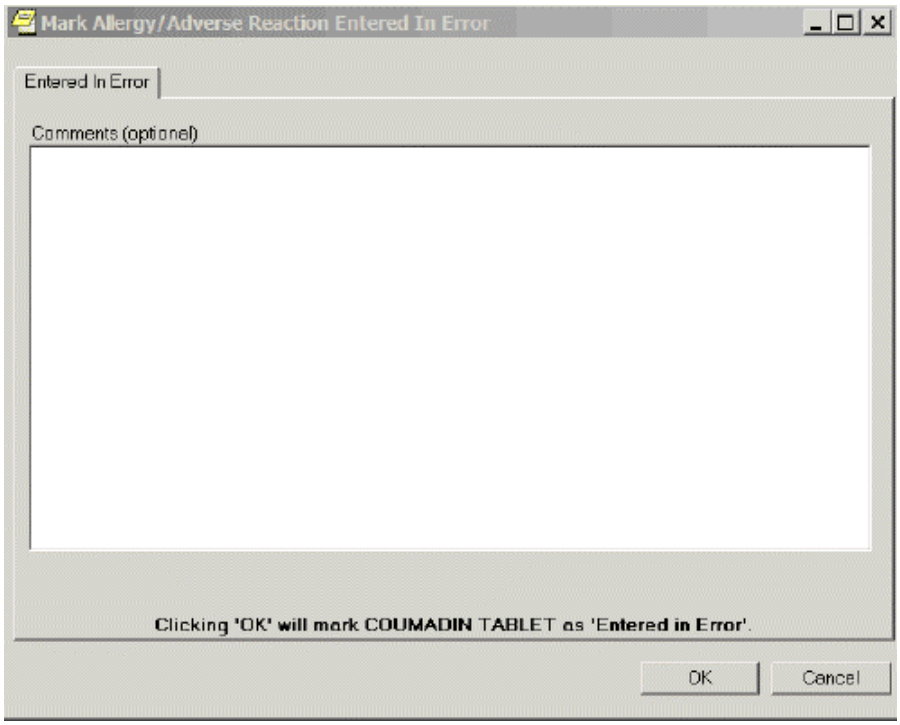
Marking Allergies as Entered in Error

CPRS offers two methods for marking allergies as having been entered in error:

Method One

Take the following steps to use the first method:

1. In the Allergies/Adverse Reactions pane, place your mouse pointer over an erroneously entered causative agent and right-click to display a menu.
2. From this menu, select Mark selected allergy as entered in error. CPRS displays the *Mark Allergy/Adverse Reaction Entered In Error* dialog box.



3. If your site has activated the Comments feature, you may (optionally) type comments in the **Comments (optional)** text box.

NOTE: If your site hasn't enabled the *Comments* feature, CPRS disables the dialog, which in this case is named **Comments (disabled)**.

4. Click **OK**. CPRS displays an **Are you Sure?** dialog.
5. If you are sure the causative agent was entered in error, click **Yes.** CPRS removes the causative agent from the **Allergies/Adverse Reactions** pane and from the list of allergies it displays when you click *Allergies* in the **Postings** pane.

NOTE: CPRS also generates a Progress Note when an allergy is marked "Entered in Error". When this note is signed by the originator or an administrative update user, the note will be viewable by all CPRS users.

Method Two

Follow these steps to use the second method:

1. Left-click a causative agent (or highlight using the Tab and arrow keys and press <Enter>) that appears in the Allergies/Adverse Reactions pane. CPRS displays a dialog that contains detailed information about the allergy or adverse reaction. This dialog includes three buttons.
2. Click the Entered in Error button. CPRS displays the *Mark Allergy/Adverse Reaction Entered In Error* dialog.
3. If your site has activated the Comments feature, you may (optionally) type comments in the **Comments (optional)** text box.

NOTE: If your site hasn't enabled the *Comments* feature, CPRS disables the dialog, which in this case is named **Comments (disabled)**.

4. Click **OK**. CPRS displays an **Are you Sure?** dialog.
5. If you are sure the causative agent was entered in error, click **Yes.** CPRS removes the causative agent from the **Allergies/Adverse Reactions** pane and from the list of allergies it displays when you click *Allergies* in the **Postings** pane.

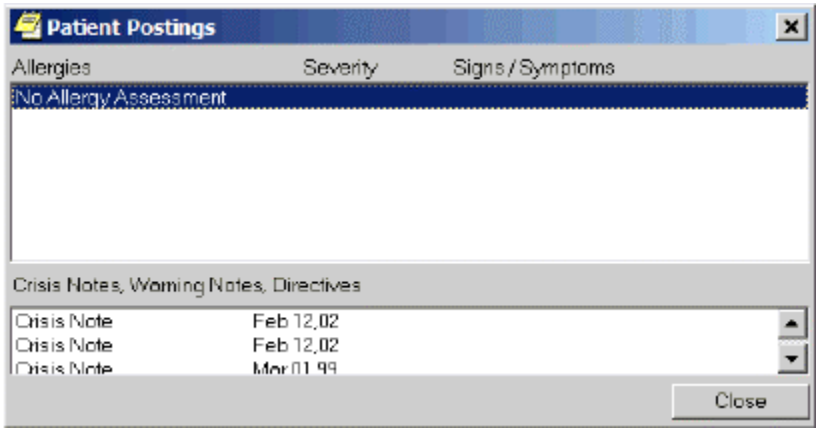
NOTE: CPRS also generates a Progress Note when an allergy is marked "Entered in Error". When this note is signed by the originator or an administrative update user, the note will be viewable by all CPRS users.

Reviewing and Creating Postings

Postings contain critical patient-related information that hospital staffs need to be aware of. The **Postings** button is visible on all tabs of the CPRS GUI window and is always located in the upper right corner of the window.

To view a posting using the Postings (CWAD) button, follow these steps:

1. Click the **Postings** button (available from any tab). CPRS displays the *Patient Postings* dialog.



2. From the *Patient Postings* dialog, click to select the particular posting in which you are interested.

To view the posting from the Cover Sheet, follow these steps:

3. On the Cover Sheet tab, click on a specific posting that appears in the Postings pane to display the details.
4. When finished, click Close.

Creating Postings

You create the following types of postings by creating progress notes using note titles that your site's IRM staff has configured for this purpose. (Check with your site's IRM staff if you don't know which note titles create which types of postings.)

- Clinical Warning (which is the same as Warning)
- Crisis Note
- Directive
- Warning

For example, to create a posting for a crisis note, take the following steps:

1. Select the Notes tab.
2. Select New Note. CPRS displays the Progress Note Properties dialog.
3. In the Progress Note Title pane, select CRISIS NOTE.
4. In the Date/Time of Note field, select a date.
5. In the Author field, select an author.
6. Click OK**.**
7. From the main menu, select File **|** Refresh Patient Information. CPRS displays the letter C (for crisis note) on the Postings button and, in the Postings pane on the Cover Sheet Tab, displays the title *Crisis Note* and the date you selected for the note.

To create a posting for an allergy or adverse reaction, enter the allergy from either the **Cover Sheet** tab or the **Orders** tab. (See "Entering Allergies" in the "Assessing, Entering, and Reviewing Allergies/Adverse Reactions" section of this manual or "Entering Allergies from the Orders Tab" in the "Orders" section of this manual, respectively.)

NOTE: Although you may be able to enter progress notes for allergies and adverse reactions, doing so does not create an *Allergies* postings. As mentioned above, you can create *Allergies* postings only by entering allergies via the **Cover Sheet** or **Orders** tab. Furthermore, CPRS cannot perform order checks on allergies you document via progress notes.

Entering Allergies from the Orders tab

Although allergies and adverse reactions are not orders and CPRS does not display them on the Orders tab, you can enter allergies and adverse reactions from the Orders tab. You can also enter allergies from the Cover Sheet tab.

To enter allergies or adverse reactions from the Orders tab, follow these steps:

1. Click the Orders tab.
2. Select Allergies from the Write Orders pane.
   The *Allergy Reactant Lookup* dialog appears.

   NOTE: Your site may have defined and configured other order menus to include allergy-entry dialogs. Regardless of the allergy-entry menu you select, if you haven't entered encounter information, the *Location for Current Activities* dialog appears before the *Allergy Reactant Lookup* dialog appears. You must complete the *Location for Current Activities* dialog before proceeding.
3. Type the causative agent in the search field. (At a minimum, you must enter the first three letters of the agent.)
4. Click Search.
   Matching agents appear in the Select from one of the following items window. If the causative agent you typed does not match any of the agents currently available for your site, CPRS displays the *Causative Agent Not On File* dialog box, from which you can select one of the following options:
   a. Yes: Use this option to request that the causative agent be added for your site. When you click Yes, CPRS displays the *Enter Optional Comments* dialog, which enables you to type additional comments (optional), such as the signs or symptoms that occurred as a result of contact with this causative agent, or whether you observed these symptoms firsthand. After you type your comments, click Continue. CPRS then sends to members of your site's GMRA Request New Reactant mail group a message that includes the following items:

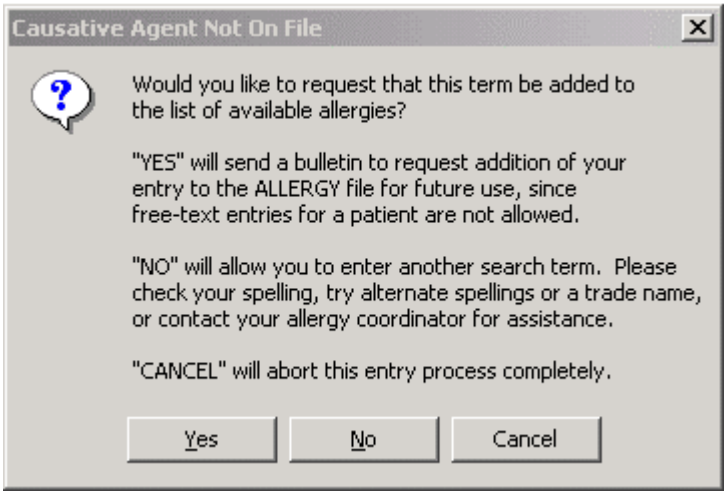
      - The causative agent you attempted to enter
      - The name of the patient for whom you attempted to make this entry
      - Your name, title, and contact information
      - Your comments

      Members of your site's GMRA Request New Reactant mail group will review this message and, if appropriate, add the causative agent to your site's ALLERGIES file.

      NOTE: If your site's IRM staff has not yet added members to your site's GMRA Request New Reactant mail group, CPRS displays the following message:

d. **No**: Use this option if you want to try an alternate spelling or trade name for your causative agent, or if you want to type another causative agent.

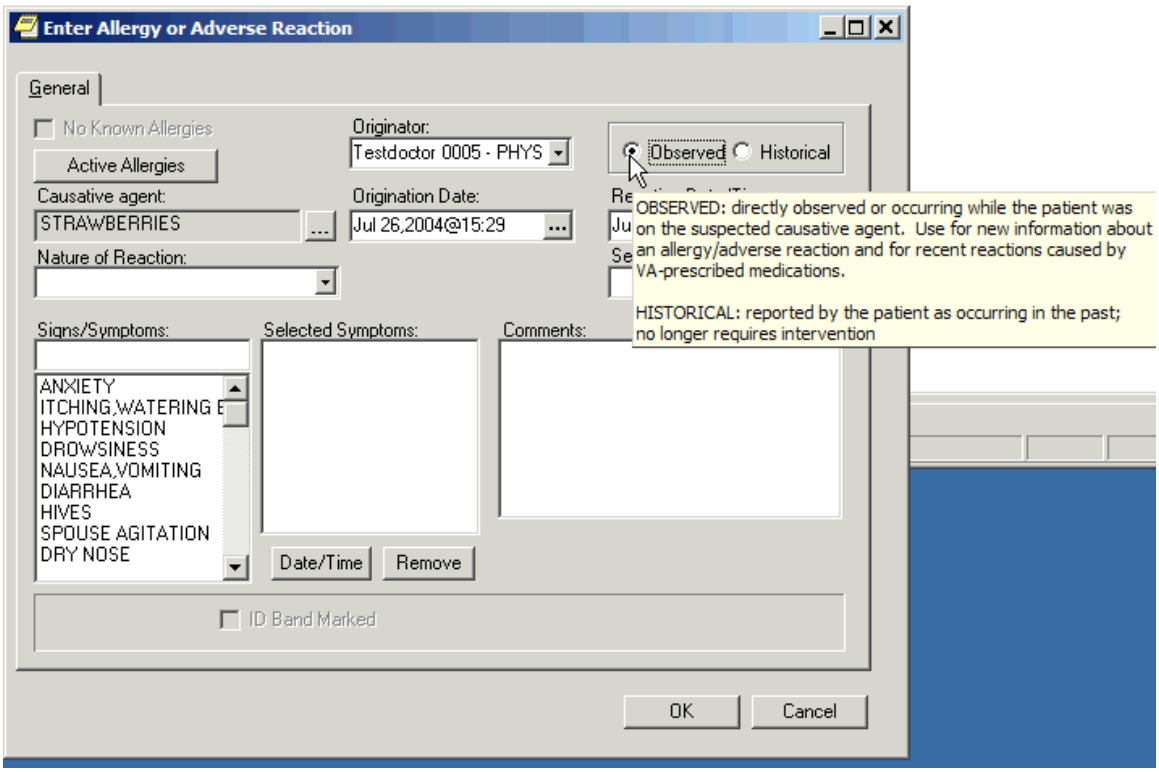
e. **Cancel**: Use this option if you want to cancel your allergy order.



5. If the causative agent you typed matches an agent that is currently available for your site, select the agent. (Click + to expand a heading.)

   NOTE: With CPRS GUI 24 or later, you may not add free-text allergies. If you select an item under the "Add new free-text allergy" heading, CPRS displays the *Causative Agent Not On File* dialog. (See Step 5 above.)

6. Click OK.
   The *Enter Allergy or Adverse Reaction* dialog appears.



NOTE: You can view a patient's current allergies or adverse reactions by clicking the Active Allergies button.

7. Using the Originator and Origination Date boxes, select an originator and origination date, respectively.
8. Use the Observed or Historical option button to indicate whether the entry is for an observed or historical allergy, respectively. (When you point your mouse at either of these buttons, CPRS displays a hover hint explaining the observed and historical options.)
9. Use the Nature of Reaction list box to select a reaction type.

   The Nature of Reaction (also known as mechanism)can be Allergy, Pharmacologic, or Unknown. An allergic reaction occurs because the patient is sensitive to a causative agent, regardless of the amount the patient is exposed to. A pharmacologic (non-allergic) reaction occurs when the patient is sensitive to an agent under certain conditions, such as exposure to a large amount. Unknown is provided if you are not sure what mechanism to enter.

   Note: Allergies are a subset of adverse reactions. All allergies are adverse reactions, but not all adverse reactions are allergies.

10. If you are entering an observed allergy, use the Reaction Date/Time and Severity boxes to select a reaction date, time, and severity. (The Severity text box is not visible for historical allergies. When the Severity box is visible, CPRS displays a **?** button next to it. If you click this button, CPRS displays text that provides information about available severity selections.)

    Note: CPRS does not allow you to enter future dates for observed reactions

11. Using the Signs/Symptoms list box, select one or more signs or symptoms. The signs and symptoms you select appear in the Selected Symptoms pane.

12. To associate a date and time with a symptom (optional), click to select the symptom in the **Selected Symptoms** pane.

13. Click the **Date/Time** button located below the **Selected Symptoms** pane. CPRS displays the **Select Date/Time** dialog, from which you can select the date and time that the symptom first appeared.

14. To remove a sign or symptom (optional), select the symptom in the **Selected Symptoms** pane and click the **Remove** button located beneath the pane.

15. Type comments for the allergy in the Comments text box.

16. If you have marked the allergy or adverse reaction on the patient's chart and/or identification (ID) band (or if you know someone else has performed this task), select the ID Band Marked checkbox.

    NOTE: CPRS activates the ID Band Marked checkbox only for inpatients and then only if your site's IRM staff has set a parameter indicating your site wants to track this information. Depending on whether your IRM staff has set related parameters, if you do not select activated ID Band Marked checkbox, the system may send a bulletin notifying a mail group that the patient's allergy or adverse reaction is not marked on his or her ID band.

17. Click OK.

Although CPRS does not display allergy-related assessments on the Orders tab, you can also enter an assessment of no known allergies (NKA) from the Orders tab.

To enter a no-known allergies assessment from the Orders tab, follow these steps:

1. Click the Orders tab.
2. Select Allergies from the Write Orders pane. You will have to select a location. The *Allergy Reactant Lookup* dialog appears.

   NOTE: Your site may have defined and configured other order menus to include allergy-entry dialogs. Regardless of the allergy-entry menu you select, if you haven't entered encounter information, the *Location for Current Activities* dialog appears before the *Allergy Reactant Lookup* dialog appears. You must complete the *Location for Current Activities* dialog before proceeding.

3. Select the No Known Allergies check box in the lower portion of the dialog box.
4. Click OK.
5. The Enter Allergy/Adverse Reaction dialogue appears. The No Known Allergies indicator in the upper left will contain a check mark.
6. Click OK.

NOTE: You can also enter a no-known-allergies assessment from the Cover Sheet tab.

Glossary

Adverse Reaction	Any condition precipitated by a drug that requires patient treatment, admission or transfer; prompts a specialty consultation; or causes injury or death. Every allergy is an adverse reaction, but every adverse reaction is not an allergy.
Adverse Reaction Only	Something that is an adverse reaction but not an allergy.
Adverse Reaction Tracking	The software package that stores and reports the patient allergy or adverse reaction data.
Allergy	A state of hypersensitivity induced by exposure to a certain agent
Application	A system of computer programs and files that have been specifically developed to meet the requirements of a user or group of users. Examples of VISTA applications are the MAS and Nursing modules
Application Coordinator	The person responsible for implementing a set of computer programs (application package) developed to support a specific functional area such as Nursing, MAS, etc.
ART See Adverse Reaction Tracking.	
Causative Agent	The name of the item that caused the patient to have a reaction (e.g., penicillin).
Date/Time Chart Marked	In ART, this field indicates when the patient's chart has been marked to indicate this allergy or adverse reaction.
Date/Time ID Band Marked	In ART, this field indicates when the patient ID band or bracelet has been marked to indicate this allergy or adverse reaction
Date/Time MD Notified	A field in ART that indicates when the primary physician has been alerted about a patient allergy or adverse reaction.
Dechallenge	Discontinuation/removal of allergen.
GMR Allergies File	A file of allergies/adverse reactions that are used by ART. The file number is 120.82.
GMRA MARK CHART bulletin	Warning that is generated when Date/Time Chart Marked field is left blank. This warning indicates that someone has to record this allergy or adverse reaction in the patient's chart.
GMRA MARK CHART mail group	This is the group of people who are charged with the responsibility to see that all data entered into ART gets recorded in the patient's chart.
GMRA VERIFY ALLERGY bulletin	Warning that an allergy or adverse reaction has been signed off (completed) by the originator and that it is ready for the verification process.
GMRA-VERIFY ALLERGY security key	Should be given to all verifiers in ART. Allows a verifier access to the verification process
Historical	An allergy that has been stated by some source versus one that has actually been witnessed by some personnel at this facility.
Ingredient file	A file (#50.416) that contains generic drugs that are components of various drug products.
Likelihood	A measure of the probability that an allergy or adverse reaction was the cause of the patient problems indicated by the

	signs/symptoms. This field is calculated via an FDA algorithm
Local Drug File	The list of medications used at a particular VA facility. This file is also sent out by the VISTA Pharmacy developers. The file number is 50.
Mechanism	In the context of ART, this is an indicator of whether the data for a patient is an adverse reaction only, or an allergy.
National Drug File	This file is a list of drug products available, which includes specific information for each product. Information included for the products are trade name, NDC number, manufacturer, VA Drug Class code, dosage form, route of administration, strength and units, ingredients, ingredient strength and units, package code, package size, package type, VA product name and VA generic name.
Observed	An allergy or adverse reaction that has actually been witnessed by some personnel at this facility.
Patient Allergies File	The file where the patient allergy/adverse reaction data is stored in ART. The file number of this file is 120.8.
Rechallenge	Reintroduction of allergen after dechallenge.
Severity	This is an index of how the allergy/adverse reaction affected the patient.
Sign/Symptom	Something that could be subjectively or objectively measured that indicates an allergy or adverse reaction.
Sign/Symptoms File	A list of signs/symptoms that can be selected for a patient allergy or adverse reaction. The file number is 120.83.
Top Ten Signs/Symptoms	A site-configurable set of indicators of an allergy or adverse reaction that is used to expedite data entry of these indicators.
Treatment	This is some lab test or drug intervention that was performed as a result of an allergy or adverse reaction.
True Allergy	Something that is an allergy, which implies that it is also an adverse reaction.
VA Drug Classification System file	A file (#50.605) that contains the VA Drug Classification codes and their descriptions. Each drug product in the National Drug file is assigned a primary code, which is part of the information stored for each drug product in the National Drug file.
Verification	The process of reviewing and approving the data entered by some clinical user. This process is done by a verifier.
Verifier	A person who has the GMRA-VERIFY ALLERGY security key. This person can perform verification of patient data in ART.

Appendix 1: National GMR Allergies File (120.82) Entries

ADHESIVE TAPE
ALCOHOL
ANIMAL HAIR
ANISE OIL
ANTIRABIES SERUM
ASCORBIC ACID
ASPARTAME
ASPIRIN
AUROTHIOGLUCOSE (SESAME OIL)
BANANA
BCG VACCINE
BENZALKONIUM CHLORIDE
BISMUTH SUBSALICYLATE
BOTULISM ANTITOXIN
BROAD BEANS
BUTTERSCOTCH FLAVORING
CAFFEINE
CALCITONIN, SALMON
CAPSAICIN
CARROTS
CETYLPYRIDINIUM
CHEESE
CHICKEN
CHOCOLATE
CINNAMON OIL
CITRATED CAFFEINE
CITRUS
CLOVE OIL
COCOA
COD LIVER OIL
CORN
COTTONSEED OIL
DAIRY PRODUCTS
DIGOXIN IMMUNE FAB (OVINE)
DIPHTHERIA ANTITOXIN, EQUINE
DIPHTHERIA TOXOID
DUST
EGGS
ESTRADIOL CYPIONATE
F D & C BLUE #2
F D & C GREEN #6
F D & C RED #3
F D & C RED #40
F D & C RED #40 LAKE
F D & C YELLOW #6

F D & C YELLOW #6 LAKE
FAT EMULSIONS
FIGS
FISH
FLUPHENAZINE DECANOATE
FOOD PRESERVATIVES
FOOD STARCH, MODIFIED
GELATIN
GOLD SODIUM THIOMALATE
HEPARIN SODIUM (BEEF LUNG)
HEPARIN SODIUM (PORK)
HERRING
HORSE SERUM
INSULIN
IODINE
IRON FILLINGS
LACTOSE
LICORICE
MALTOSE
METHYL SALICYLATE
METHYLCELLULOSE
MILK
MOLD
MONOSODIUM GLUTAMATE
NAFARELIN ACETATE
NANDROLONE, ETC
NUTS
OTHER ALLERGY/ADVERSE REACTION
PARA-AMINOBENZOIC ACID
PARABEN
PEACHES
PEANUT OIL
PEPPERMINT
PINEAPPLE
PLUMS
POLLEN
POLYSORBATE
PORK
POTASSIUM IODIDE
POTATO
POULTRY
POVIDONE IODINE
PSYLLIUM
RABIES IMMUNE GLOBULIN
RED FOOD DYE
SACCHARIN
SAFFLOWER OIL
SALICYLAMIDE
SALICYLIC ACID
SESAME OIL
SHELL FISH

SHRIMP
SOY BEANS
SOY SAUCE
STRAWBERRIES
SULFITES
SUNFLOWER OIL
TARTARIC ACID
TESTOSTERONE
TOMATO
VANILLA
VASOPRESSIN TANNATE (IN OIL)
WHEAT
YEAST
YOGURT

Appendix 2: National Sign/Symptoms (120.83) File Entries

AGITATION
AGRANULOCYTOSIS
ALOPECIA
ANAPHYLAXIS
ANEMIA
ANOREXIA
ANXIETY
APNEA
APPETITE, INCREASED
ARRHYTHMIA
ASTHENIA
ASTHMA
ATAXIA
ATHETOSIS
BRACHYCARDIA
BREAST ENGORGEMENT
BRONCHOSPASM
CARDIAC ARREST
CHEST PAIN
CHILLS
COMA
CONFUSION
CONGESTION,NASAL
CONJUNCTIVAL CONGESTION
CONSTIPATION
COUGHING
DEAFNESS
DELIRIUM
DELUSION
DEPRESSION
DEPRESSION, MENTAL
DEPRESSION, POSTICTAL
DERMATITIS
DERMATITIS, CONTACT
DERMATITIS, PHOTOALLERGENIC
DIAPHORESIS
DIARRHEA
DIPLOPIA
DISTURBED COORDINATION
DIZZINESS
DREAMING, INCREASED
DROWSINESS
DRY MOUTH
DRY NOSE
DRY THROAT
DYSPNEA

DYSURIA
ECCHYMOSIS
ECG CHANGES
ECZEMA
EDEMA
EPIGASTRIC DISTRESS
EPISTAXIS
ERYTHEMA
EUPHORIA
EXCITATION
EXTRASYSTOLE
FACE FLUSHED
FACIAL DYSKINESIA
FAINTNESS
FATIGUE
FEELING OF WARMTH
FEVER
GALACTORRHEA
GENERALIZED RASH
GI REACTION
GLAUCOMA
GYNECOMASTIA
HALLUCINATIONS
HEADACHE
HEART BLOCK
HEMATURIA
HEMOGLOBIN, INCREASED
HIVES
HYPERSENSITIVITY
HYPERTENSION
HYPOTENSION
IMPAIRMENT OF ERECTION
IMPOTENCE
INAPPROPRIATE PENILE ERECTION
INSOMNIA
IRRITABILITY
ITCHING, WATERING EYES
JUNCTIONAL RHYTHM
LABYRINTHITIS, ACUTE
LACRIMATION
LDH, INCREASED
LETHARGY
LEUKOCYTE COUNT, DECREASED
LIBIDO, DECREASED
LIBIDO, INCREASED
MIOSIS
MYOCARDIAL INFARCTION
NAUSEA, VOMITING
NERVOUSNESS, AGITATION
NEUTROPHIL COUNT, DECREASED
NIGHTMARES

OPTIC ATROPHY
ORGASM, INHIBITED
ORONASALPHARYNGEAL IRRITATION
OTHER REACTION
PAIN, JOINT
PALPITATIONS
PANCYTOPENIA
PARESTHESIA
PARKINSONIAN-LIKE SYNDROME
PHOTOSENSITIVITY
POSSIBLE REACTION
PRIAPISM
PROLONGED PENILE ERECTION
PRURITIS
PTOSIS
PURPURA
RALES
RASH
RASH, PAPULAR
RESPIRATORY DISTRESS
EnterROGRADE EJACULATION
RHINITIS
RHINORRHEA
RHONCHUS
S-T CHANGES, TRANSIENT
SEIZURES
SEIZURES, TONIC-CLONIC
SELF-DEPRECATION
SEVERE RASH
SHORTNESS OF BREATH
SINUS BRACHYCARDIA
SNEEZING
SOMNOLENCE
SPEECH DISORDER
SWELLING (NON-SPECIFIC)
SWELLING-EYES
SWELLING-LIPS
SWELLING-THROAT
SYNCOPE
TACHYCARDIA
THROMBOCYTOPENIA
TREMORS
URINARY FLOW, DELAYED
URINARY FREQUENCY
URINARY FREQUENCY, INCREASED
URINARY EnterENTION
URTICARIA
UVEITIS
VERTIGO
VISION,BLURRED
VISUAL DISTURBANCES

VOMITING
WEAKNESS
WEIGHT GAIN
WHEEZING

Appendix 3: GUI 25 Release Notes – ART

The following functionality is available only to sites that have installed OR*3.0*195, OR*3.0*216, and GMRA*4.0*21 Sites that have not installed these patches will continue to receive the ART functionality that exists in CPRS GUI 24.

- **Allergies No Longer Entered as Orders (NOIS: SHR-0603-71103)** – At sites that have installed the patches listed above, users can no longer enter allergies and adverse reactions as orders that are placed in the *ORDERS* file. Patch OR*3.0*216 exports a modified order-dialog entry—*GMRAOR ALLERGY*—in the *ORDER DIALOG* file. This entry enables CPRS to interact directly with the Adverse Reaction Tracking (ART) package (i.e., CPRS adds new allergies and adverse reactions directly into the ART package as users submit them.)

With supporting patches OR*3.0*216 and GMRA*4.0*21, CPRS GUI 25 does not display allergy information on the **Orders** tab. It displays allergy information only on the **Cover Sheet** tab. Nevertheless, users can still enter allergy information from the **Orders** tab by selecting **Allergies** in the **Write Orders** pane. (i.e., users can still go to a familiar place to enter allergies.)

In addition, users can no longer select **OTHER ALLERGY/ADVERSE REACTION** as causative agent, nor can they select **OTHER REACTION** as a sign/symptom. Changes to the ART package have eliminated these items as choices. These changes mark a continuing effort to end free-text and unspecific entries.

If 'type of causative agent' references the field ALLERGY TYPE, the GUI interface doesn't allow the user to enter this information. It is determined internally by the selection made during the Reactant lookup process. "OTHER REACTION" is still selectable from the signs/symptoms list; free text entries of signs/symptoms are allowed.

Also, CPRS now requires users to enter information about the nature of the reaction that they are documenting (**Allergy**, **Pharmacological**, or **Unknown**).

Finally, CPRS GUI 24 introduced a dialog through which users can request that a causative agent be added to their site's *ALLERGIES* file. Users access this dialog via a warning that pops up when they attempt to enter a free-text causative agent. The warning dialog asks users to indicate—by clicking either its **YES** or **NO** button—if they want to send a causative-agent inclusion request. In CPRS GUI 24, the default button was **YES**. In CPRS GUI 25, the default button is **NO**. Furthermore, when users click the system **X** button (located in the top right-hand corner of each screen) to exit any of the screens that comprise the inclusion-request dialog, CPRS now cancels the request action.

- **Allergy Changes on the Cover Sheet** - CPRS now enables users to perform several ART-related actions from the **Cover Sheet** tab—including the following:
    - **Enter new allergy**
    - **Mark selected allergy as entered in error**
    - **Mark patient as having "No Known Allergies" (NKA)**

When users right-click within the **Allergies/Adverse Reactions** pane, CPRS displays a menu offering the three selections listed in the previous paragraph (or a sub-set, depending on the current Allergy information recorded for the patient). When users left click to select one of the allergies listed within the **Allergies/Adverse Reactions** pane, CPRS opens a window that displays details about this allergy-as it always has. However, this window now includes two additional buttons: **Add New** and **Entered in Error**. As the names of these buttons suggest, clicking them enables users to add new allergies and designate the selected allergy as entered in error, respectively. When users mark allergy entries as entered in error, the ART package notifies (via MailMan bulletins) sites' GMRA MARK CHART mail group.

Depending on how sites have configured their *GMR ALLERGIES SITE PARAMETERS* files, the ART package could also send bulletins to one or more of the following mail groups: GMRA VERIFY DRUG ALLERGY, GMRA VERIFY FOOD ALLERGY, and GMRA VERIFY OTHER ALLERGY. In addition, marking an allergy entry as entered in error triggers the Text Integration Utility (TIU) package to generate an Allergy/Adverse Reaction progress note that is sent to the originator to document the erroneous entry. Whether users enter new allergies via the **Cover Sheet** or **Orders** tab, CPRS displays an **Enter Allergy or Adverse Reaction** dialog, through which users enter adverse reactions and allergies directly into the ART package. This dialog includes several changes, including the following changes:

- CPRS no longer allows users to enter future origination dates or future dates for observed allergies; if users attempt to enter future dates for these items, CPRS prevents them from doing so when they click OK to submit their allergy entries
- A new button containing a question mark is associated with the Severity dialog; when users select this button, CPRS displays a text box defining severity selections
- CPRS displays a hover hint when users mouse over the Observed and Historical option buttons; a user group (as opposed to OI staff) specified the text of the hover-hint
- When the amount of text in the Comments dialog exceeds its viewing area, CPRS adds a scroll bar to the dialog
- Developers altered the tabbing sequence to more closely match users' expectations
- When an allergy is marked as "Entered in Error," Drug allergy, this action generates a Progress Note for the user who marked it as "entered in error" to sign. Once the user who marked the allergy as entered in error or an administrative user signs the note, all CPRS users can view the note to know that an allergy has been removed from the list.
- When an allergy is entered as an "Observed, Drug allergy," this action generates a Progress Note for the user who entered the Allergy/Adverse reaction to sign. Once the user who made the entry or an administrative user signs the note, all CPRS users can view the note.

The **Enter Allergy or Adverse Reaction** dialog also contains a new check box: **ID Band Marked**. If the patients are inpatients and the sites have set the MARK ID BAND parameter in the *GMR ALLERGY SITE PARAMETERS* file to **1 (YES)**, users can select this check box to indicate whether they have marked allergies and adverse reactions on the patient's identification (ID) bands. If users submit an allergy entry without selecting activated **ID Band Marked** check box, the ART package automatically notifies sites' GMRA MARK CHART mail group via a MailMan bulletin. *GMR ALLERGY SITE PARAMETER* file settings also determine to which verification mail groups (GMRA VERIFY DRUG ALLERGY, GMRA VERIFY FOOD

ALLERGY, or GMRA VERIFY OTHER ALLERGY) the ART package sends MailMan bulletins when users enter specific combinations of allergy information.

Deleting an assessment of NKA

From within the ART package, it is now possible to delete an assessment of NKA.

When you select a patient for entering/editing allergies and that patient doesn't have any active allergies on file, the “Does this patient have any known allergies or adverse reactions?” prompt is presented to you. If the patient has no assessment, there is no default answer. If the patient has been assessed as NKA, the default is NO.

In the case where the default answer is NO (meaning, the patient is NKA), you may enter an @ sign to indicate that the assessment should be deleted and the patient should be returned to the 'not assessed' state. This would be used in those rare cases where an assessment is erroneously assigned to the wrong patient.

Examples:

1) Patient who is currently not assessed:

```
Select PATIENT NAME: ARTPATIENT,ONE        1-20-57    456334567
YES     MILITARY RETIREE      THIS IS A TEST
Does this patient have any known allergies or adverse reactions? :
```

2) Patient who has been assessed as NKA:

```
Select PATIENT NAME: ARTPATIENT,ONE        1-20-57    456334567
YES     MILITARY RETIREE      THIS IS A TEST
Does this patient have any known allergies or adverse reactions? :
No//
```

At this point, if I enter a ?, I see what my choices are:

```
Choose from:
1        Yes
0        No
```

You may also enter @ to delete a previous NKA assessment and return the patient to a 'not assessed' state. Use this if the NKA assessment was previously incorrectly entered.

Does this patient have any known allergies or adverse reactions? : No//

The information regarding the use of the @ will only show if the patient is currently NKA. If they are not, then it doesn't show.

3) Finally, here's what it looks like when you delete the assessment:

```
Select PATIENT NAME: ARTPATIENT,ONE    1-20-57    456334567     YES
MILITARY RETIREE      THIS IS A TEST
Does this patient have any known allergies or adverse reactions? :
No// @
Assessment deleted.
```